

# Exhibit C-1

1 IN THE UNITED STATES DISTRICT COURT  
2 FOR THE DISTRICT OF ARIZONA  
3 - - -  
4 IN RE BARD IVC FILTERS : NO. MD-15-02641-PHX-DGC  
PRODUCTS LIABILITY LITIGATION :

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6  
7 - - -  
8 MARCH 21, 2017  
9 - - -

10 DO NOT DISCLOSE - SUBJECT TO FURTHER  
CONFIDENTIALITY REVIEW

11 Videotape deposition of MARCUS

12 D'AYALA, M.D., taken pursuant to notice, was held at  
13 the law offices of Aaronson Rappaport Feinstein &  
14 Deutsch, LLP, 600 Third Avenue, New York, New York  
15 10016, beginning at 12:45 p.m., on the above date,  
16 before Amanda Dee Maslynsky-Miller, a Certified  
17 Realtime Reporter and Notary Public in and for the  
18 State of New York.

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Page 2			Page 4		
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1            - - -	1 BY MR. MATTHEWS:
2            DEPOSITION SUPPORT INDEX	2 Q. Could you state your name, please?
3            - - -	3 A. Marcus D'Ayala.
4	4 MS. HELM: Dave, before we get
5 Direction to Witness Not to Answer	5 started, I have to address the failure to -- I just
6 Page Line    Page Line    Page Line	6 want to address on the record very quickly the
7 None	7 failure to comply with the CMO relating to the
8	8 identification of documents.
9	9 It appears that it may not be an
10 Request for Production of Documents	10 issue, based on conversations we had prior to the
11 Page Line    Page Line    Page Line	11 deposition. But on March 14th, I received a letter
12 None	12 identifying documents that have been or may be
13	13 provided to Dr. D'Ayala pursuant -- prior to his
14	14 deposition. On March 17 at 1:50 a.m., less than
15 Stipulations	15 five days before this deposition, I received a list
16 Page Line    Page Line    Page Line	16 from plaintiffs' counsel of 27 documents that you
17 7      1	17 identified that you intended to use at the
18	18 deposition, including an expert report that contains
19	19 hundreds of documents.
20 Question Marked	20 On Sunday, March 19th at 11:30 p.m.,
21 Page Line    Page Line    Page Line	21 less than two days before the deposition, I received
22 None	22 another list of 13 documents that plaintiffs may use
23	23 during the deposition. In all, plaintiffs
24	24 identified more than 40 documents, which the CMO
25	25 only allows for 40, and they've identified at least
Page 7	
1            - - -	1 40 of them after the deadline set by the court.
2            (It is hereby stipulated and agreed	2 Finally, we were served with a
3 by and among counsel that sealing, filing and	3 deposition notice that said the deposition was at
4 certification are waived; and that all objections,	4 10:00 a.m., and the subpoena to the doctor was for
5 except as to the form of the question, will be	5 1:00 p.m., and we received an amended notice
6 reserved until the time of trial.)	6 yesterday that was dated March 16th that cleared it
7            - - -	7 up.
8            VIDEO TECHNICIAN: We are now on the	8 Again, I don't think it's going to be
9 record. My name is Kevin Pollard, and I'm a	9 an issue, based on the conversation we had prior to
10 videographer for Golkow Technologies. Today's date	10 the start of the deposition. But to the extent it
11 is March 21, 2017, and the time is 12:45 p.m.	11 becomes an issue, obviously, Bard is reserving our
12            This video deposition is being held	12 rights and, unfortunately, the right to reconvene if
13 in New York, New York, in the matter of CR Bard IVC	13 we have to.
14 Filters Products Liability Litigation. The deponent	14 Doctor, I hope we don't have to, but
15 is Marcus D'Ayala, MD.	15 we are under procedures and orders in this case and,
16            Counsel will be noted on the	16 unfortunately, they haven't been followed. So I
17 stenographic record. The court reporter is Amanda	17 have to take that position.
18 Miller and will now swear in the witness.	18 MR. MATTHEWS: I understand. I did
19            - - -	19 try to clear up, prior to the deposition, the
20            MARCUS D'AYALA, M.D., after having	20 documents that we anticipate using, which are quite
21 been duly sworn, was examined and testified as	21 a bit fewer than the documents identified. Some of
22 follows:	22 those identified might be used in rebuttal, if, for
23            - - -	23 instance, you ask about a certain document.
24            EXAMINATION	24 That said, we anticipate using
25            - - -	25 approximately ten documents today.

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<p>1           MS. HELM: And I understand that.</p> <p>2 But I think you understand that it is our position</p> <p>3 that the plaintiffs have failed to comply with the</p> <p>4 CMO. And, as a result, to the extent there's any</p> <p>5 prejudice to Bard, I have to reserve any rights that</p> <p>6 we have.</p>	<p>1           A. I practice at New York-Presbyterian</p> <p>2 Brooklyn Methodist Hospital, which was formerly</p> <p>3 known as New York Methodist Hospital. We were</p> <p>4 recently acquired and, hence, the name change.</p>
<p>7           MR. MATTHEWS: I understand.</p> <p>8           Are we ready to go?</p> <p>9           THE WITNESS: Yes.</p>	<p>5           Q. Okay. Is that the only hospital that</p> <p>6 you have privileges?</p>
<p>10 BY MR. MATTHEWS:</p> <p>11          Q. Let's start over.</p> <p>12          Doctor, could you state your name,</p> <p>13 please?</p>	<p>7          A. It is.</p> <p>8          Q. Today I think we'll just call it New</p> <p>9 York Methodist, if that's okay.</p>
<p>14          A. Marcus D'Ayala.</p> <p>15          Q. And what do you do, sir?</p> <p>16          A. I'm a vascular surgeon in clinical</p> <p>17 practice in Brooklyn, New York.</p> <p>18          Q. And you live in Brooklyn?</p> <p>19          A. I live in Long Island and Brooklyn,</p> <p>20 correct.</p> <p>21          Q. Okay. Have you given a deposition</p> <p>22 before today?</p> <p>23          A. I have.</p> <p>24          Q. All right. In what matter or</p> <p>25 matters?</p>	<p>10          A. Perfectly fine.</p> <p>11          Q. It seems quite a bit easier.</p> <p>12          MR. LERNER: I'm sure they'll be</p> <p>13 happy if you just call it Methodist.</p> <p>14          MR. MATTHEWS: All right. We'll just</p> <p>15 call it Methodist then. Fair enough.</p> <p>16 BY MR. MATTHEWS:</p> <p>17          Q. Are you a full-time clinician?</p> <p>18          A. I am.</p> <p>19          Q. You do not teach?</p> <p>20          A. I do teach.</p> <p>21          Q. What percentage of your time do you</p> <p>22 spend teaching?</p> <p>23          A. I would estimate it to be about 20</p> <p>24 percent.</p> <p>25          Q. So Methodist is a teaching hospital?</p>
Page 11	Page 13
<p>1          A. I have been called to give</p> <p>2 depositions in legal matters involving several</p> <p>3 patients. I don't have any specific recollection of</p> <p>4 any of them. None of these matters ever came to</p> <p>5 court or were dealt with in any other way other than</p> <p>6 just being disposed.</p> <p>7          I'm not so sure as to what the legal</p> <p>8 term is, but a couple of depositions, and that was</p> <p>9 the extent of it. No more than two or three, I</p> <p>10 would say.</p> <p>11          Q. Have you ever testified in a case</p> <p>12 involving a medical device?</p> <p>13          A. No.</p> <p>14          Q. Have you ever consulted with any</p> <p>15 medical device companies?</p> <p>16          A. I'm not so sure I understand your</p> <p>17 question.</p> <p>18          Q. Have you been a consultant to any</p> <p>19 company that manufacturers medical devices?</p> <p>20          A. In terms of providing them with</p> <p>21 expert advice regarding their products? No.</p> <p>22          Q. Are you currently a consultant with</p> <p>23 any medical device company?</p> <p>24          A. I am not.</p> <p>25          Q. Where do you practice medicine?</p>	<p>1          A. It is.</p> <p>2          Q. All right. The other 80 percent of</p> <p>3 the time, you are a clinician; that is, you spend</p> <p>4 time treating patients?</p> <p>5          A. Correct.</p> <p>6          Q. All right.</p> <p>7          A. With a small amount of that time</p> <p>8 dedicated to administration of our division.</p> <p>9          Q. Okay. Doctor, I represent Sherr-Una</p> <p>10 Booker. She was a patient of yours back in 2007.</p> <p>11 You, at that time, implanted a G2, Bard G2 IVC</p> <p>12 filter.</p> <p>13          I suspect you do not recall her</p> <p>14 personally?</p> <p>15          A. I do not.</p> <p>16          Q. Have you had a chance to look at the</p> <p>17 records, your records, of the implant and the</p> <p>18 procedure that took place back in 2007?</p> <p>19          A. I have.</p> <p>20          Q. Other than the review of the medical</p> <p>21 record, your medical record wherein you implanted</p> <p>22 this Bard G2 in Ms. Booker, did you look at any</p> <p>23 other medical records?</p> <p>24          A. I did.</p> <p>25          But for the sake of clarity, I must</p>

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<p>1 say it's not my record, it's the hospital's record.</p> <p>2 Q. So you reviewed some hospital record</p> <p>3 as well as your own medical record --</p> <p>4 MR. LERNER: No. No.</p> <p>5 BY MR. MATTHEWS:</p> <p>6 Q. -- at one point?</p> <p>7 MR. LERNER: It's not his records,</p> <p>8 it's only the hospital record. He doesn't have his</p> <p>9 own personal private records for the patient.</p> <p>10 BY MR. MATTHEWS:</p> <p>11 Q. Right. So you only reviewed the</p> <p>12 hospital records?</p> <p>13 A. Correct.</p> <p>14 Q. Okay. Any --</p> <p>15 A. Just so as to be clear in this</p> <p>16 regards, I saw her as an inpatient, in hospital, and</p> <p>17 I had an opportunity to review those records. I did</p> <p>18 not see her as an outpatient or in my private</p> <p>19 practice.</p> <p>20 Q. Okay. In reviewing those records,</p> <p>21 were you able to identify the doctor who actually</p> <p>22 ordered the implant?</p> <p>23 A. I'm not so sure I fully understand</p> <p>24 that question. I can tell you that I know the</p> <p>25 doctor that asked us to see this patient in</p>	<p>1 Q. Have you reviewed anything else in</p> <p>2 preparation for your deposition today? You told us</p> <p>3 about the Methodist medical record.</p> <p>4 Any other documents or anything at</p> <p>5 all prior to this deposition?</p> <p>6 A. There are two documents that I</p> <p>7 reviewed just this morning, the Methodist medical</p> <p>8 record and the medical record from, I believe it was</p> <p>9 Gwinnett Hospital.</p> <p>10 MS. HELM: Gwinnett.</p> <p>11 THE WITNESS: Gwinnett Hospital.</p> <p>12 MR. MATTHEWS: Do you have those with</p> <p>13 you.</p> <p>14 MR. LERNER: I have them in my</p> <p>15 office, yes. They were copies that you guys</p> <p>16 provided to us.</p> <p>17 MR. MATTHEWS: All right. I just</p> <p>18 wanted to make sure what we were talking about. If</p> <p>19 there's something else in there, I would --</p> <p>20 MR. LERNER: On the record, they were</p> <p>21 provided to me by your office.</p> <p>22 MS. HELM: In the flurry?</p> <p>23 MR. LERNER: Yes.</p> <p>24 MR. MATTHEWS: Very good.</p> <p>25 BY MR. MATTHEWS:</p>
<p>1 consultation.</p> <p>2 Q. Who was that doctor?</p> <p>3 A. Dr. Dean Martin.</p> <p>4 Q. And what type of doctor is Dr. Dean</p> <p>5 Martin?</p> <p>6 A. He is an obstetrician/gynecologist.</p> <p>7 Q. Had he referred or consulted with you</p> <p>8 prior to that time?</p> <p>9 MR. LERNER: About different</p> <p>10 patients, you mean?</p> <p>11 MR. MATTHEWS: Yes, about other</p> <p>12 patients.</p> <p>13 THE WITNESS: Yes.</p> <p>14 BY MR. MATTHEWS:</p> <p>15 Q. Had he consulted with you about the</p> <p>16 use of IVC filters on prior occasions?</p> <p>17 A. Yes.</p> <p>18 Q. Today I'm here to ask you, really,</p> <p>19 about three areas of inquiry; your treatment of Ms.</p> <p>20 Booker, the decision to use the G2 filter, and then</p> <p>21 what warnings you had, prior to implanting the</p> <p>22 filter, about the risks and the benefit of the G2</p> <p>23 filter.</p> <p>24 Do you understand those three areas?</p> <p>25 A. Yes.</p>	<p>1 Q. Doctor, you brought a C.V. with you</p> <p>2 today. We're going to mark that as Exhibit-1 to</p> <p>3 your deposition.</p> <p>4 MR. MATTHEWS: And I will mark in</p> <p>5 succession deposition exhibits, and we'll attach</p> <p>6 those to your deposition today, all right?</p> <p>7 A. Sure.</p> <p>8 - - -</p> <p>9 (Whereupon, Exhibit-1, Curriculum</p> <p>10 Vitae, Marcus D'Ayala, was marked for</p> <p>11 identification.)</p> <p>12 - - -</p> <p>13 BY MR. MATTHEWS:</p> <p>14 Q. Is Exhibit-1 a current, up-to-date,</p> <p>15 accurate copy of your C.V.?</p> <p>16 A. Yes.</p> <p>17 Q. It says you're the chief of vascular</p> <p>18 surgery at Methodist Hospital, previously at</p> <p>19 University of Texas Health Science Center in San</p> <p>20 Antonio. Prior to that, chief of vascular surgery,</p> <p>21 Bronx VA Hospital.</p> <p>22 That's all correct?</p> <p>23 A. Yes.</p> <p>24 Q. In terms of IVC filter literature,</p> <p>25 that is, a study or medical document that you</p>
Page 15	Page 17

Page 18	Page 20
<p>1 produced, I have seen that you have two studies      2 concerning the IVC filters; is that correct?      3           MR. LERNER: Are you talking about in      4 his publication list?</p> <p>5           MR. MATTHEWS: His publication      6 section of his C.V.</p> <p>7           THE WITNESS: Yes, that is correct.</p> <p>8 BY MR. MATTHEWS:</p> <p>9       Q. You don't have anything more current      10 that may be not listed on here?</p> <p>11      A. No, I do not.</p> <p>12      Q. You were provided a copy of a      13 confidentiality or protective order, and I think we      14 had asked your attorney if you had signed that prior      15 to this deposition. And I don't know if that      16 occurred.</p> <p>17      MR. LERNER: He wasn't provided with      18 it, I was. And I didn't ask him to sign it. I      19 apologize, that's just my omission. So if you have      20 one, I suspect he's happy to sign it now.</p> <p>21      I looked at it, Doctor, there's --</p> <p>22      THE WITNESS: If Mr. Lerner is happy,      23 I'm happy.</p> <p>24      MR. LERNER: I'm never happy, so      25 don't go by that standard.</p>	<p>1           MS. HELM: Yes, sir. He's going to      2 be shown -- apparently going to be shown some      3 internal documents from Bard, and he just has to      4 agree to maintain that confidentiality.</p> <p>5           MR. LERNER: Yes. I said you're      6 never going to talk about this outside the room.</p> <p>7           MR. MATTHEWS: Thank you, Doctor.</p> <p>8 BY MR. MATTHEWS:</p> <p>9       Q. Doctor, before we talk about      10 Sherr-Una Booker, I'd like to talk about your      11 experience and knowledge of IVC filters prior to the      12 implant in June of 2007, okay?</p> <p>13      A. Okay.</p> <p>14      Q. I know that's asking you to look      15 quite a bit back in the past. At the same time,      16 it's important that we explore what you knew and      17 when you knew it, okay?</p> <p>18           Is it fair to say before you use any      19 medical device, the benefits have to outweigh the      20 risk of that device; is that a fair statement?</p> <p>21      A. Yes.</p> <p>22      Q. And that's how you practice medicine?</p> <p>23      A. Yes.</p> <p>24      Q. You look at benefits versus risks?</p> <p>25      A. Yes.</p>
Page 19	Page 21
<p>1           MR. MATTHEWS: We are going to -- I      2 am handing this to your lawyer Mr. Lerner.</p> <p>3           MR. LERNER: For your benefit, I was      4 amused on your client's questionnaire answer, it      5 says Carnarsie High School in the Bronx; Carnarsie's      6 in Brooklyn. No one in New York would ever accept      7 that as accurate. You guys should know that.</p> <p>8           MR. MATTHEWS: Note taken. I'm from      9 Wisconsin, so what do I know?</p> <p>10          MR. LERNER: So he's signing Page 16,      11 correct, is that what you'd like? Or do you want      12 18?</p> <p>13          MS. HELM: He needs to sign --</p> <p>14          MR. LERNER: 18 or 16 or both?</p> <p>15          MS. HELM: I'm sorry. It's just 16.</p> <p>16          MR. LERNER: Doctor, at the bottom,      17 it's self-explanatory.</p> <p>18          Do you have a pen?</p> <p>19          THE WITNESS: No, I do not.</p> <p>20          Thank you.</p> <p>21          MR. LERNER: So what you're signing      22 away is don't talk about this outside of this room.</p> <p>23          THE WITNESS: Understood.</p> <p>24          MR. LERNER: Except to me, I guess.</p> <p>25          THE WITNESS: The 21st?</p>	<p>1       Q. You have to know the extent of the      2 risks in order to make an assessment of whether that      3 product, whether you're placing it in a person, is      4 going to outweigh the risk, that is, the benefits      5 outweigh the risks?</p> <p>6           MS. HELM: Object to the form.</p> <p>7           THE WITNESS: That is correct.</p> <p>8 BY MR. MATTHEWS:</p> <p>9       Q. If there are significant risks, you      10 need to give informed consent to your patients if      11 there's potential for a serious injury or death,      12 correct?</p> <p>13      A. Yes.</p> <p>14      Q. That type of information is crucial      15 for you, if there is a significant potential for      16 serious injury or death, to communicate to your      17 patient?</p> <p>18      MS. HELM: Object to the form.</p> <p>19      THE WITNESS: Yes.</p> <p>20 BY MR. MATTHEWS:</p> <p>21      Q. All right. Let me ask you about the      22 frequency of risk, and that is, the risk of serious      23 injury or death.</p> <p>24           Is it important to you, as a treating      25 doctor that implants devices in a patient, what the</p>

<p style="text-align: right;">Page 22</p> <p>1 frequency of that risk is, whether it's one in a      2 million or one in ten? Is that an important -- is      3 that important information for you in determining      4 the risk versus benefit analysis?</p> <p>5 A. Yes.</p> <p>6 MS. HELM: I need to object to the      7 form.</p> <p>8 MR. LERNER: You need to let him      9 finish his question before you give an answer.</p> <p>10 THE WITNESS: My apologies.</p> <p>11 MR. MATTHEWS: Do you need to take a      12 call?</p> <p>13 THE WITNESS: Could I, please? I'm      14 so sorry. I'll be right with you.</p> <p>15 MR. MATTHEWS: We'll take a break.</p> <p>16 VIDEO TECHNICIAN: We are now off the      17 record. The time is 1:02.</p> <p>18 - - -</p> <p>19 (Whereupon, a brief recess was      20 taken.)</p> <p>21 - - -</p> <p>22 VIDEO TECHNICIAN: We are now back on      23 the record. The time is 1:06.</p> <p>24 BY MR. MATTHEWS:</p> <p>25 Q. Doctor, there was an objection. I</p>	<p style="text-align: right;">Page 24</p> <p>1 THE WITNESS: Yes.</p> <p>2 BY MR. MATTHEWS:</p> <p>3 Q. Doctor, you only saw Ms. Booker in      4 June of 2007; is that correct?</p> <p>5 A. Yes.</p> <p>6 Q. Prior to getting contacted about this      7 case, for this case, you had no idea of the      8 condition of her; is that true?</p> <p>9 A. Yes.</p> <p>10 Q. You did not know that she had      11 multiple filter fractures and fragments that      12 embolized and traveled to her heart?</p> <p>13 MS. HELM: Object to the form.</p> <p>14 Mischaracterizes testimony.</p> <p>15 MR. LERNER: And I don't -- when did      16 he have the knowledge -- I'm a little confused by      17 your question.</p> <p>18 BY MR. MATTHEWS:</p> <p>19 Q. Let me ask it this way: Prior to      20 today, have you had any information given to you      21 that she had fracture -- a fracture of that G2 that      22 embolized and traveled to her heart?</p> <p>23 MS. HELM: Object to the form.</p> <p>24 THE WITNESS: No.</p> <p>25 BY MR. MATTHEWS:</p>
<p style="text-align: right;">Page 23</p> <p>1 want to make clear the question to you.</p> <p>2 Is it important to you, as a      3 clinician that implants medical devices, to know the      4 frequency of which a device fails?</p> <p>5 A. Yes.</p> <p>6 MS. HELM: Objection to the form.</p> <p>7 BY MR. MATTHEWS:</p> <p>8 Q. It's important because you have to      9 weigh that potential for failure and serious injury      10 with the benefit that the patient may have from the      11 product, correct?</p> <p>12 MS. HELM: Object to the form.</p> <p>13 THE WITNESS: Yes.</p> <p>14 BY MR. MATTHEWS:</p> <p>15 Q. All right. What about the risk of      16 serious injury, that is, the severity of the injury?      17 Is that also important for you to know, when doing a      18 risk/benefit analysis, whether you use a product or      19 not?</p> <p>20 A. Yes.</p> <p>21 Q. And those two individual points of      22 analysis, that is, frequency and severity of adverse      23 events, both of those are used in your prescribing      24 decisions?</p> <p>25 MS. HELM: Object to the form.</p>	<p style="text-align: right;">Page 25</p> <p>1 Q. You've not heard that?</p> <p>2 A. No.</p> <p>3 Q. You had not heard she had open heart      4 surgery?</p> <p>5 A. No.</p> <p>6 Q. Had you heard of other patients or      7 read medical records of prior patients of yours that      8 have had filter fractures?</p> <p>9 A. Yes.</p> <p>10 Q. Have those patients suffered from      11 factors that have embolized to their heart?</p> <p>12 A. Yes.</p> <p>13 Q. Do they suffer from pericarditis when      14 this occurs? Have your prior patients suffered from      15 pericarditis?</p> <p>16 A. No.</p> <p>17 Q. Now, I want to be clear so the jury      18 understands.</p> <p>19 The typical scenario when you're      20 contacted by, in this case Dr. Dean Martin, who is      21 an OB/GYN, who contacted you to consult with whether      22 Dean's patient -- Dr. Martin's patient needed a      23 filter or not. That is kind of the typical      24 scenario.</p> <p>25 You're not treating the patient. You</p>

<p style="text-align: right;">Page 26</p> <p>1 don't own the patient, but you're consulting with a      2 doctor who is treating the patient; is that a normal      3 scenario?</p> <p>4 MS. HELM: Object to the form.</p> <p>5 THE WITNESS: Yes.</p> <p>6 BY MR. MATTHEWS:</p> <p>7 Q. So oftentimes, you'll treat a patient      8 and implant a filter, as an example, or a stent, and      9 that may be the only time that you see that patient?</p> <p>10 A. Yes, but that's not the norm.</p> <p>11 Q. It's not the norm.</p> <p>12 That's what happened with Ms. Booker,      13 though, correct?</p> <p>14 A. I'm not entirely sure. What I would      15 say, that is customary for me is to see a patient      16 before a procedure, make an assessment regarding      17 whether or not that procedure is necessary, and      18 that, as you alluded to, typically involves a      19 complex risk/benefit analysis.</p> <p>20 And there are many factors that come      21 into play when we make those risk/benefit analyses,      22 and they include things like the natural history of      23 their disease process, their age, their      24 comorbidities and their life expectancy, the      25 proposed risks of whatever intervention we have or</p>	<p style="text-align: right;">Page 28</p> <p>1 will not treat that patient, in other words, that      2 patient is being treated by someone else?</p> <p>3 A. Yes.</p> <p>4 Q. All right. And if there's a decision      5 to remove a filter, that decision is often someone      6 else's, whether it's a primary care physician,      7 whether it's the orthopedic surgeon, whether it's      8 the internist that's treating that patient, that      9 decision oftentimes isn't even yours?</p> <p>10 MS. HELM: Object to the form.</p> <p>11 BY MR. MATTHEWS:</p> <p>12 Q. Is that true? Is that basically      13 true?</p> <p>14 MS. HELM: Same objection.</p> <p>15 THE WITNESS: I'm not entirely sure      16 that I agree with that. I think we play an      17 important role in retrieving these filters, or at      18 least we try to.</p> <p>19 So the whole issue of filter      20 retrieval is one that has been an evolution over the      21 years. And today it's part of our practice to      22 advise these patients to return for follow-up to      23 have filters retrieved, if it's possible to do so      24 and do so safely.</p> <p>25 So a number of requirements must be</p>
<p style="text-align: right;">Page 27</p> <p>1 are planning for them and so on.</p> <p>2 So my practice is such that I will      3 see somebody before, make an assessment as to what      4 is best, discuss treatment options with them, move      5 forward if a procedure is required, and then see      6 them, typically within a day afterwards to make sure      7 that there were no complications as a result of our      8 procedure.</p> <p>9 It's also customary for us to -- for      10 me, at least, to ask my patients to come back for      11 follow-up visits, at least one, within 30 days of      12 surgery or discharge from hospital.</p> <p>13 Q. Okay. So to summarize, I think, what      14 you just said, you will typically see a patient      15 pre-operatively?</p> <p>16 A. Correct.</p> <p>17 Q. You will make a risk/benefit      18 analysis, you will perform the procedure, you will      19 see a patient post-op, and then you will want to see      20 that patient at least once within 30 days post-op?</p> <p>21 A. Correct.</p> <p>22 Q. Did I get that pretty much right?</p> <p>23 A. Pretty much right.</p> <p>24 Q. Okay. Now, oftentimes is it typical,      25 let me ask this, that after the 30 day follow-up you</p>	<p style="text-align: right;">Page 29</p> <p>1 met for us to retrieve these filters.</p> <p>2 BY MR. MATTHEWS:</p> <p>3 Q. I'm going to back up, if I could,      4 because now we're talking about 2017 --</p> <p>5 A. Correct.</p> <p>6 Q. -- and 2007 is the time frame. So      7 I'm going to ask a different question.</p> <p>8 A. Okay.</p> <p>9 Q. Back in 2007 when you were implanting      10 in particular the G2, the G2 had only been cleared      11 for permanent implantation; is that correct?</p> <p>12 A. Correct.</p> <p>13 Q. So you were implanting this filter as      14 a permanent filter in 2007, correct?</p> <p>15 A. Correct.</p> <p>16 Q. At that time in 2007, that filter,      17 when you implanted it in Ms. Booker, was intended as      18 a permanent filter, correct?</p> <p>19 MS. HELM: Object to the form.</p> <p>20 THE WITNESS: Correct.</p> <p>21 BY MR. MATTHEWS:</p> <p>22 Q. All right. Well, let's talk about,      23 then, a different subject, and that is your history      24 with the use of filters.</p> <p>25 Can you tell the jury when you first</p>

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<p>1 started using inferior vena cava filters, IVC</p> <p>2 filters?</p> <p>3 A. Sure. During my vascular training.</p> <p>4 Q. What year was that?</p> <p>5 A. That would have been at the Mount</p> <p>6 Sinai Hospital in '97, '98.</p> <p>7 Q. Do you recall which filters you used</p> <p>8 at that time?</p> <p>9 A. Not particularly.</p> <p>10 Q. Do you recall any of the filters you</p> <p>11 used prior to the Bard G2?</p> <p>12 A. Yes, I do.</p> <p>13 Q. Could you tell us what you used?</p> <p>14 A. Before using the Bard filter, we used</p> <p>15 a filter by the Cordis Corporation, a division of</p> <p>16 Johnson &amp; Johnson, known as the TRAPEASE. We moved</p> <p>17 away from using the TRAPEASE filter when it became</p> <p>18 clear that it was associated with a high incidence</p> <p>19 of caval thrombosis.</p> <p>20 Q. Any other filters that you used?</p> <p>21 A. I believe we transitioned away from</p> <p>22 the Bard filter towards the Cook filter after it</p> <p>23 became clear to us that there were certain problems</p> <p>24 with the Bard filter as well.</p> <p>25 I cannot specifically recall the</p>	<p>1 filters.</p> <p>2 Q. Do you recall the time frame when you</p> <p>3 moved away from Bard filters?</p> <p>4 A. I do not.</p> <p>5 Q. Clearly it was after 2007, because</p> <p>6 you were still implanting the G2 in 2007, correct?</p> <p>7 A. Correct.</p> <p>8 Q. Were you called upon by a sales rep</p> <p>9 or somebody that's known as a detailer from Bard</p> <p>10 that came to your hospital to talk to you --</p> <p>11 A. Yes.</p> <p>12 Q. -- about their filters?</p> <p>13 Do you recall that sales rep?</p> <p>14 A. We had a number throughout the years</p> <p>15 from different corporations, so if you could be a</p> <p>16 little bit more specific.</p> <p>17 Q. Well, I guess I'm referring to a</p> <p>18 sales rep by the name of Ferrara.</p> <p>19 Do you recall a sales rep by the name</p> <p>20 of Ferrara?</p> <p>21 A. Robert Ferrara?</p> <p>22 Q. Ferrara, I'm sorry.</p> <p>23 A. I do.</p> <p>24 Q. Was he in your offices from time to</p> <p>25 time to talk about the Recovery and the G2?</p>
<p>1 timelines as to when these things were done.</p> <p>2 Q. Did you ever use the Bard Recovery</p> <p>3 filter?</p> <p>4 A. I believe I did.</p> <p>5 Q. All right. So you used the Bard</p> <p>6 Recovery, the Bard G2, the Cordus TRAPEASE. And you</p> <p>7 said the Cook filters.</p> <p>8 Do you recall which Cook filters you</p> <p>9 used?</p> <p>10 A. We use the Günther Tulip and right</p> <p>11 now it's a variation of it called the Cook Select,</p> <p>12 C, as in Charles, E-L-E-C-T.</p> <p>13 Q. You said you moved away from the Bard</p> <p>14 filter because of problems associated with it,</p> <p>15 correct?</p> <p>16 A. Yes.</p> <p>17 MS. HELM: Object to the form.</p> <p>18 BY MR. MATTHEWS:</p> <p>19 Q. What were the problems associated</p> <p>20 with the Bard that -- the reason that you moved away</p> <p>21 from it?</p> <p>22 A. There is a database known as the</p> <p>23 MAUDE database and it was becoming clear that there</p> <p>24 were numerous reports in the literature of filter</p> <p>25 fragmentation and filter migration with these</p>	<p>1 A. Uh-huh.</p> <p>2 Q. Yes?</p> <p>3 A. Yes.</p> <p>4 Q. I'm sorry. You've got to answer</p> <p>5 aloud for her.</p> <p>6 A. Yes.</p> <p>7 Q. Were you ever told by Mr. -- is it</p> <p>8 Ferrara?</p> <p>9 A. Uh-huh.</p> <p>10 Q. -- Mr. Ferrara that Bard had a crisis</p> <p>11 management plan, as early as 2004, to deal with the</p> <p>12 high rates of AEs, that being, adverse events,</p> <p>13 perforation, fracture and migration?</p> <p>14 MS. HELM: Object to the form.</p> <p>15 THE WITNESS: No.</p> <p>16 BY MR. MATTHEWS:</p> <p>17 Q. Were you ever told that Bard</p> <p>18 conducted an investigation in 2004 into the high</p> <p>19 number or large number of adverse events of the</p> <p>20 Recovery done by an independent investigator?</p> <p>21 MS. HELM: Object to the form.</p> <p>22 THE WITNESS: No.</p> <p>23 BY MR. MATTHEWS:</p> <p>24 Q. Were you ever sent a letter by the</p> <p>25 company that talked to you or -- I'm sorry, that</p>

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<p>1 informed you about the results of this      2 investigation, this independent investigation by      3 Bard?</p> <p>4 MS. HELM: Object to the form.</p> <p>5 THE WITNESS: No.</p> <p>6 BY MR. MATTHEWS:</p> <p>7 Q. Were you ever told, either by letter      8 or by Mr. Ferrara, that there was a 530 percent      9 higher fracture rate than other filters on the      10 market with the Bard Recovery?</p> <p>11 MS. HELM: Object to the form.</p> <p>12 THE WITNESS: No.</p> <p>13 BY MR. MATTHEWS:</p> <p>14 Q. Were you ever told that there was a      15 1,200 percent higher risk of death from the Recovery      16 fracture and embolization to the heart than other      17 filters on the market?</p> <p>18 MS. HELM: Object to the form.</p> <p>19 THE WITNESS: No.</p> <p>20 BY MR. MATTHEWS:</p> <p>21 Q. In 2004 and 2005, clearly two years      22 prior to implanting Ms. Booker with the G2, would      23 that have been important information for you to      24 know? Assuming that that was information that was      25 known to Bard, is that something that you would want</p>	<p>1 MS. HELM: Do you have a copy for me?      2 MR. MATTHEWS: This is a health      3 hazard evaluation dated December 17th, 2004.      4 - - -      5 (Whereupon, Exhibit-2,      6 BPVE-01-01019821-825, Health Hazard Evaluation,      7 Dated 12/17/04, was marked for identification.)      8 - - -      9 THE WITNESS: Thank you.</p> <p>10 BY MR. MATTHEWS:</p> <p>11 Q. Let me show you, if you could turn.      12 Just so we're clear on the record, this is a health      13 hazard evaluation from David Ciavarella, MD, who I      14 believe was the vice president of clinical trials --      15 clinical affairs, dated December 17th, 2004, to Doug      16 Uelmen, BPV QA. And this is Recovery Filter      17 Consultants Report, and I would turn your attention      18 to the second page --</p> <p>19 A. Okay.</p> <p>20 Q. -- under Number 2. It says that, The      21 consultant's analysis of the reports of Bard -- to      22 Bard of adverse events associated with the Recovery,      23 along with competitors' information available via      24 the MAUDE and IMS databases, showed the following:      25 Reports of death, filter migration, IVC perforation</p>
<p style="text-align: center;">Page 35</p> <p>1 to have known?</p> <p>2 A. Yes.</p> <p>3 MS. HELM: Object to the form.</p> <p>4 THE WITNESS: Can I interrupt for one      5 second? I just wanted to clarify one other point.      6 Previously you asked me how many      7 publications I had regarding filters. And there's      8 actually a third publication that I had forgotten,      9 and I see it here in my C.V. It's one in which a      10 filter migrated to the heart. And with your      11 question before, I remember you asking me about      12 filters migrating to the heart.</p> <p>13 BY MR. MATTHEWS:</p> <p>14 Q. That was a case study, correct?</p> <p>15 A. That was a case report, that's      16 correct.</p> <p>17 Q. Yes, case report. I did read that.      18 Thank you.</p> <p>19 MS. HELM: Do you mind telling us      20 which number that is?</p> <p>21 THE WITNESS: That would be 28 to 32      22 under publications.</p> <p>23 BY MR. MATTHEWS:</p> <p>24 Q. Let me show you what's been marked as      25 Exhibit Number 2.</p>	<p style="text-align: center;">Page 37</p> <p>1 and filter fracture associated with the Recovery      2 filter were seen in the MAUDE database at reporting      3 rates that were 4.6, 4.4, 4.1 and 5.3 higher,      4 respectively, than reporting rates for all other      5 filters.</p> <p>6 Doctor, this is dated December 17th,      7 2004. Would this have been important information      8 for you to know, that is, a doctor who is implanting      9 Recovery filters, that those filters had a greater      10 risk of fracture that's four and five times higher      11 than the competitor filters?</p> <p>12 MS. HELM: Object to the form.</p> <p>13 THE WITNESS: Yes.</p> <p>14 BY MR. MATTHEWS:</p> <p>15 Q. Is that the type of information that      16 would influence your prescribing habits, whether you      17 would use that filter, a Bard filter, or another      18 filter?</p> <p>19 MS. HELM: Object to the form.</p> <p>20 THE WITNESS: Yes.</p> <p>21 BY MR. MATTHEWS:</p> <p>22 Q. Let me show you what's been marked as      23 Exhibit-3, which is the Recovery filter migration,      24 Remedial Action Plan, dated January 4, 2005.      25 - - -</p>

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<p>1                   (Whereupon, Exhibit-3,</p> <p>2 BPVE-01-01019773-784, Recovery Filter Migration,</p> <p>3 Dated 1/4/05, was marked for identification.)</p> <p>4                   - - -</p> <p>5 BY MR. MATTHEWS:</p> <p>6       Q. Again, this is a full two and-a-half</p> <p>7 years prior to implanting Ms. Booker with the G2.</p> <p>8                   And I would turn your attention to</p> <p>9 the first, second, third, fourth, fifth page. It</p> <p>10 says, actually, 1 of 7 on the fifth page of that</p> <p>11 document.</p> <p>12     A. I'm sorry, could you --</p> <p>13     Q. At the bottom under Roman III.</p> <p>14                  It says, Identification of the</p> <p>15 problem: As part of the ongoing evaluation of RNF,</p> <p>16 Recovery Nitinol filter, Bard requested an</p> <p>17 independent study of the risks and benefits of the</p> <p>18 RNF, with an emphasis on its use in bariatric</p> <p>19 surgery and trauma patients. A consultant was</p> <p>20 retained for this purpose and reported the</p> <p>21 following: The MAUDE database maintained by the FDA</p> <p>22 was reviewed. The reporting rates between the RNF</p> <p>23 and aggregates of the other commercialized vena cava</p> <p>24 filters were compared.</p> <p>25      A, in the MAUDE dataset, the RNF</p>	<p>1 to know prior to implanting a Recovery filter?</p> <p>2       A. Yes.</p> <p>3                  MS. HELM: Object to the form.</p> <p>4 BY MR. MATTHEWS:</p> <p>5       Q. Do you know what the term</p> <p>6 "statistically significant" means?</p> <p>7       A. I do.</p> <p>8       Q. And that's an important</p> <p>9 epidemiological statement, correct?</p> <p>10                  MS. HELM: Object to the form.</p> <p>11                  THE WITNESS: Statistical statement,</p> <p>12 yes.</p> <p>13 BY MR. MATTHEWS:</p> <p>14      Q. Doctor, at the Methodist Hospital in</p> <p>15 2007, did you have more than one filter at your</p> <p>16 disposal? That is, you talked about, I think you</p> <p>17 told me, you had the TRAPEASE, you had the Tulip,</p> <p>18 and you had the Recovery, and you had the select.</p> <p>19                  Were all of those available back in</p> <p>20 2007, do you recall?</p> <p>21      A. No.</p> <p>22      Q. Do you know which were available?</p> <p>23      A. The G2.</p> <p>24      Q. That was the only one available in</p> <p>25 the hospital?</p>
<p>1 demonstrated a consistent statistically significant</p> <p>2 and potentially clinically important higher rate of</p> <p>3 reporting of adverse events in several analyzed</p> <p>4 categories.</p> <p>5                  B, given the pattern of reported</p> <p>6 events, a higher rate of death reports seem related</p> <p>7 to filter movement and filter embolization.</p> <p>8                  You referenced the MAUDE database</p> <p>9 earlier in questions, Doctor. Is that information</p> <p>10 important to you as a doctor that is implanting the</p> <p>11 Recovery filter?</p> <p>12      MS. HELM: Object to the form.</p> <p>13      MR. LERNER: Which information?</p> <p>14      MR. MATTHEWS: That is A and B that I</p> <p>15 just read.</p> <p>16      MS. HELM: Object to the form.</p> <p>17      MR. LERNER: But you questioned him,</p> <p>18 you said you referenced the MAUDE database before.</p> <p>19 Your question then becomes confusing. I'm asking</p> <p>20 you to clarify it.</p> <p>21      MR. MATTHEWS: All right. I'll</p> <p>22 strike it and ask another question.</p> <p>23 BY MR. MATTHEWS:</p> <p>24      Q. In looking at A and B, Doctor, is</p> <p>25 that the type of information that's important to you</p>	<p>1 A. It's very likely, although I could</p> <p>2 not say with certainty that a single filter would be</p> <p>3 stocked, yes.</p> <p>4       Q. You couldn't say that a single filter</p> <p>5 was used at the time; is that what your testimony</p> <p>6 is?</p> <p>7       A. My testimony is that it is common for</p> <p>8 us to, for certain periods, do business with a</p> <p>9 particular vendor and that vendor stock whichever</p> <p>10 product we're using at the time, whether it be a</p> <p>11 filter or a stent or something other.</p> <p>12      It's possible that other devices were</p> <p>13 in the hospital, but it's more likely that a single</p> <p>14 product was being bought, stocked and used at the</p> <p>15 hospital for IVC filters.</p> <p>16      Q. Let me ask you this: As chief of</p> <p>17 vascular surgery at Methodist Hospital, did you have</p> <p>18 input on the formulary or -- in the formulary as to</p> <p>19 which products would be stocked or which filters</p> <p>20 would be used at the hospital?</p> <p>21      A. Yes.</p> <p>22      Q. So if you, the head of vascular</p> <p>23 surgery said, you know, I don't want this filter but</p> <p>24 I want these other two filters, or what have you,</p> <p>25 you could have had an impact on that decision?</p>

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<p>1 A. I could have, yes.</p> <p>2 Q. Can you tell the jury about how many</p> <p>3 filters you would place annually starting in the</p> <p>4 early 2000s?</p> <p>5 And I admit that's a tough question,</p> <p>6 I know. But if you could give me a ballpark, let's</p> <p>7 say starting in 2005, two years prior to implanting</p> <p>8 Ms. Booker?</p> <p>9 A. I would have to go back and look at</p> <p>10 those numbers, which I'm sure are available. But I</p> <p>11 would say over 100 --</p> <p>12 Q. You personally --</p> <p>13 A. -- annually.</p> <p>14 Q. -- or your department?</p> <p>15 A. Our division, of which I do roughly</p> <p>16 70 percent of the clinical volume. So a significant</p> <p>17 number.</p> <p>18 Q. Do you have a medical opinion on</p> <p>19 which filter failure, if you will, was considered</p> <p>20 the most serious --</p> <p>21 MS. HELM: Object to the form.</p> <p>22 BY MR. MATTHEWS:</p> <p>23 Q. -- between filter failures, that is,</p> <p>24 KILT, fracture, perforation, migration?</p> <p>25 MR. LERNER: Are you talking -- what</p>	<p>1 THE WITNESS: No.</p> <p>2 BY MR. MATTHEWS:</p> <p>3 Q. Is that the type of information you</p> <p>4 would expect a manufacturer that sets out to make a</p> <p>5 decision, or at least look at the MAUDE information</p> <p>6 to determine filter fracture compared to other</p> <p>7 filters on the market, is that the type of</p> <p>8 information you want to know about?</p> <p>9 MS. HELM: Object to the form.</p> <p>10 THE WITNESS: Yes. But it's a bit</p> <p>11 more complicated in the sense that my understanding</p> <p>12 of the MAUDE database is that it is a voluntary</p> <p>13 database. It's not legally required for a physician</p> <p>14 to report a problem with an implant or a product,</p> <p>15 although you could argue that it is ethically</p> <p>16 required. As with any database, it has problems</p> <p>17 with regards to vetting of data, with regards to</p> <p>18 accuracy of data.</p> <p>19 So if a concern existed regarding a</p> <p>20 particular product, yes, I think that should be</p> <p>21 brought forth and studied, scientifically studied</p> <p>22 and addressed.</p> <p>23 BY MR. MATTHEWS:</p> <p>24 Q. At a bare minimum, the MAUDE database</p> <p>25 would be a signal, a red flag --</p>
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<p>1 time period are you talking about now?</p> <p>2 MR. MATTHEWS: Well, that was kind of</p> <p>3 a general question as to filters in general. So I</p> <p>4 will leave that open.</p> <p>5 BY MR. MATTHEWS:</p> <p>6 Q. Whether you have a medical opinion</p> <p>7 from your practice, from your reading, from your</p> <p>8 research, from your treatment of patients, as to</p> <p>9 which filter failure would be the most dangerous,</p> <p>10 producing the most serious injury to a patient.</p> <p>11 MS. HELM: Object to the form.</p> <p>12 THE WITNESS: I do.</p> <p>13 BY MR. MATTHEWS:</p> <p>14 Q. What's your opinion?</p> <p>15 A. Obviously, all complications are bad,</p> <p>16 although caval thrombosis can be devastating in</p> <p>17 terms of lower extremity edema and dysfunction. I</p> <p>18 think that migration or fracture are more serious</p> <p>19 events.</p> <p>20 Q. Were you ever told, at any time prior</p> <p>21 to today and being shown some documents about the</p> <p>22 MAUDE database, that Bard evaluated specifically the</p> <p>23 MAUDE database to compare their filter with others</p> <p>24 in 2004?</p> <p>25 MS. HELM: Object to the form.</p>	<p>1 MS. HELM: Object to the form.</p> <p>2 BY MR. MATTHEWS:</p> <p>3 Q. -- a red flag that should cause and</p> <p>4 promote more research into whether a product is safe</p> <p>5 and effective?</p> <p>6 A. Agree.</p> <p>7 Q. Doctor, you obviously have read IFUs,</p> <p>8 instructions for use, in your practice?</p> <p>9 A. I have.</p> <p>10 Q. I'm sure you probably have read more</p> <p>11 than you care to talk about today, and I'm really</p> <p>12 only going to talk about one.</p> <p>13 A. Okay.</p> <p>14 Q. In that regard, though, how many</p> <p>15 products, medical devices, do you think that you</p> <p>16 implant in your practice? And maybe I should just</p> <p>17 talk about 2007 because that was the time frame in</p> <p>18 which you implanted this filter.</p> <p>19 In 2007, how many different medical</p> <p>20 devices were you using in your practice to implant</p> <p>21 in patients?</p> <p>22 A. I'm trying to come up with some crude</p> <p>23 numbers in my head to answer your question</p> <p>24 accurately. I would say that it's exceedingly</p> <p>25 common for us to use -- well, I would say that it</p>

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<p>1 depends upon what you consider to be a product, 2 right? 3         If you're talking about sutures, 4 well, obviously, that goes into everybody. If 5 you're talking about implants, grafts, stents, 6 filters, stent grafts, I would say it occupies a 7 very prominent role in our practices today, as well 8 as in 2007. I would estimate well over 50 percent 9 of our cases requires some sort of implant, if not 10 75 percent. So a large number of our patients have 11 prosthetic implants, yes.</p> <p>12         Q. So probably more than 50 different 13 products?</p> <p>14         A. Yes, that's safe to say.</p> <p>15         Q. To that extent, when you look at an 16 IFU, in part you rely on that because that comes 17 from the manufacturer and you expect that to include 18 the risks and benefits of the product; is that true?</p> <p>19         MS. HELM: Object to the form. 20 You're leading, Dave. 21         MR. MATTHEWS: I am leading. 22         MS. HELM: Yeah, but you don't -- you 23 don't have him on cross. 24         MR. MATTHEWS: Well, we can talk 25 about that.</p>	<p>1             I can't prove beyond the shadow of a 2 doubt that there wasn't one after that, but I don't 3 think there was. 4             MR. LERNER: I wasn't arguing with 5 you. I just wanted to make clear that that was a 6 statement and not a question. 7             MR. MATTHEWS: It was. And it will 8 be stricken at the time of reading this deposition 9 to a jury, I'm certain. 10 BY MR. MATTHEWS: 11         Q. Doctor, I'd like to -- I don't mean 12 to interrupt you, but I would like to ask a couple 13 of specific questions about this. 14         A. Please do. 15         Q. On the second -- on the right-hand 16 column, under 7, there is a -- under E, warning, G2 17 Filter implantation, it says, Filter fracture is a 18 known complication of vena cava filters. 19         Do you see that? 20         A. I do. 21         Q. It says, There have been -- There 22 have been reports of embolization of vena cava 23 filter fragments resulting in retrieval of the 24 fragment using endovascular and/or surgical 25 techniques. Most cases of filter fracture, however,</p>
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<p>1 BY MR. MATTHEWS: 2         Q. But let me ask you, then, this 3 question, just so we're clear. 4         Do you rely, in part, on IFUs, that 5 is, instructions for use, with the products you 6 implant in patients? 7         A. Yes. 8         Q. That would include -- 9         A. In part. 10        Q. That would include implants, grafts, 11 stents, filters and other permanent devices? 12        A. Yes. 13        MR. MATTHEWS: All right. I would 14 like to mark as Exhibit-4 an IFU from the G2 filter 15 system that, on the last page, is dated 10/06. And 16 I presume this was the effective IFU in place at the 17 time of implant in 2007. 18        - - - 19        (Whereupon, Exhibit-4, IFU, G2 Filter 20 System, was marked for identification.) 21        - - - 22        MR. LERNER: Just so we're clear, 23 that last thing was a statement, not a question, 24 correct? 25        MR. MATTHEWS: That was a statement.</p>	<p>1 have been reported without any adverse clinical 2 sequelae. 3         I'd like to ask you about the first 4 sentence: Filter fracture is a known complication 5 of vena cava filters. 6         Doctor, do you read that in the IFU 7 to mean that the rates of filter fracture are 8 similar with all filters? 9         MS. HELM: Object to the form. 10        THE WITNESS: I don't read anything 11 about rate. I read something about complications 12 and about the potential for fracture. So it makes 13 no specific statements with regards to the incidence 14 of this occurrence. 15 BY MR. MATTHEWS: 16        Q. If there is evidence that the company 17 had, in 2006 or prior to that publication being sent 18 to you with the filter, and there was a showing 19 within the company of a 500 percent greater risk 20 with Bard filter compared with other filters, is 21 that the information -- the type of information that 22 you would want to know about? 23        MS. HELM: Object to the form. 24        THE WITNESS: Yes. 25 BY MR. MATTHEWS:</p>

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<p>1 Q. Would you have informed your patient,      2 based on your own ethics and your own consenting      3 habits, would you have informed your patient about      4 that, if it had said that in that IFU?</p> <p>5 MS. HELM: Object to the form.</p> <p>6 THE WITNESS: If I thought that a      7 particular problem -- I'm sorry, a particular filter      8 was a problem, was defective in some way, I unlikely      9 would use that product.</p> <p>10 BY MR. MATTHEWS:</p> <p>11 Q. Do you expect medical device      12 manufacturers to monitor the safety of their devices      13 through appropriate testing before sale of the      14 product?</p> <p>15 MS. HELM: Object to the form.</p> <p>16 THE WITNESS: Yes.</p> <p>17 BY MR. MATTHEWS:</p> <p>18 Q. Do you expect medical device      19 companies to do and perform adequately powered      20 studies looking at the safety and the efficacy of a      21 product prior to its sale?</p> <p>22 A. Yes.</p> <p>23 Q. Do you expect a medical device      24 manufacturer to do proper postmarket surveillance of      25 that product once it gets on the market and sold</p>	<p>1 A. I do --</p> <p>2 Q. -- clinical study?</p> <p>3 A. Yes.</p> <p>4 Q. When it wasn't done, it was never      5 done, Dr. Ash testified that he had been misled by      6 the company.</p> <p>7 Have you ever heard that about Dr.      8 Ash and the Recovery filter?</p> <p>9 MS. HELM: Object to the form.</p> <p>10 THE WITNESS: No.</p> <p>11 BY MR. MATTHEWS:</p> <p>12 Q. Doctor, have you ever reported a      13 filter failure to the FDA MAUDE database?</p> <p>14 A. I have not.</p> <p>15 Q. And, in fact, and you said this      16 earlier, one of the important aspects of the MAUDE      17 database, it's voluntary reporting system and the      18 only group, company or individual that has to      19 absolutely report is the manufacturer; you know      20 that, correct?</p> <p>21 A. Yes.</p> <p>22 Q. So the reporting system of doctors      23 like you who are very busy oftentimes don't report      24 to the MAUDE database filter failures --</p> <p>25 A. Yes.</p>
<p>1 en masse, to follow that and inform doctors about      2 what they see in the marketplace?</p> <p>3 A. Yes.</p> <p>4 Q. Were you ever told by Bard, Mr.      5 Ferrara or anybody at Bard, that they had observed      6 higher rates of complications with Recovery, that      7 they placed it on a temporary commercial hold? Did      8 you ever know that?</p> <p>9 MS. HELM: Object to the form.</p> <p>10 THE WITNESS: No.</p> <p>11 BY MR. MATTHEWS:</p> <p>12 Q. Were you ever told why Bard withdrew      13 the Recovery from the market?</p> <p>14 A. No.</p> <p>15 Q. Were you ever told why Bard withdrew      16 G2 from the market?</p> <p>17 A. No.</p> <p>18 Q. Do you know Dr. Murray Ash?</p> <p>19 A. No.</p> <p>20 Q. Dr. Ash testified in this case that      21 he conducted a pilot study for the Recovery filter      22 and Bard advised him it would subsequently do a      23 larger safety study.</p> <p>24 Let me ask you, do you know what a      25 pilot study is versus a clinical trial or --</p>	<p>1 Q. -- such as fracture?</p> <p>2 MS. HELM: Object to the form.</p> <p>3 THE WITNESS: Yes. But you have to      4 understand that there's -- there's other reasons for      5 that. I would just want to clarify by saying that      6 these problems are not oftentimes seen immediately.      7 So it takes some time for you to see a problem with      8 regards to fracture and/or migration. So it is not      9 uncommon for your patient to be seen or evaluated by      10 another physician in another hospital in another      11 location.</p> <p>12 So the fact that I have not reported      13 any events to MAUDE implies that I have not seen any      14 immediate failures with the filters that I have used      15 in my practice, which is the case.</p> <p>16 BY MR. MATTHEWS:</p> <p>17 Q. If I understood what you just said,      18 that oftentimes the failure will happen down the --      19 down the line --</p> <p>20 A. Correct, yes.</p> <p>21 Q. -- and you won't know about the      22 failure?</p> <p>23 A. Correct.</p> <p>24 Q. Which is exactly like Ms. Booker, you      25 didn't know anything about her failure?</p>

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<p>1 A. That's exactly right.</p> <p>2 Q. And you have not undertaken to</p> <p>3 determine how many Recovery filters or G2 filters</p> <p>4 you have implanted; is that fair?</p> <p>5 A. That's very fair.</p> <p>6 Q. And you have not undertaken the task</p> <p>7 of determining what's happened with those patients</p> <p>8 into the future?</p> <p>9 A. Correct.</p> <p>10 Q. You could never tell us, like, you</p> <p>11 know, I implanted 100 and half of them or 80 percent</p> <p>12 of them are great without problems, because you just</p> <p>13 don't know?</p> <p>14 A. That's right.</p> <p>15 Q. Have you ever received a -- what's</p> <p>16 called a Dear Doctor letter, sometimes called a Dear</p> <p>17 Healthcare Provider letter, from Bard concerning its</p> <p>18 Recovery or G2 filters?</p> <p>19 A. Not that I recall.</p> <p>20 Q. You know what that is, a Dear Doctor</p> <p>21 letter, Dear Healthcare Provider letter, safety</p> <p>22 alert?</p> <p>23 A. I would make some assumptions, but</p> <p>24 not truly.</p> <p>25 Q. We talked about risk/benefit analysis</p>	<p>1 MS. BLAS: I do.</p> <p>2 BY MR. MATTHEWS:</p> <p>3 Q. And this is a paper you wrote along</p> <p>4 with these other doctors, correct?</p> <p>5 A. Yes.</p> <p>6 Q. All right. Have you seen this in a</p> <p>7 while?</p> <p>8 A. No, I haven't looked at it in quite</p> <p>9 some time.</p> <p>10 Q. Well, this isn't a test. I just</p> <p>11 wanted to ask a couple of questions about it.</p> <p>12 A. Sure.</p> <p>13 Q. Concurrent Prophylactic Placement</p> <p>14 Inferior Vena Cava Filter in Gastric Bypass, what</p> <p>15 we're talking about is during and after placement of</p> <p>16 inferior vena cava with patients that have had lap</p> <p>17 bands or band surgery, whether there was a benefit</p> <p>18 with the use of a filter with those patients; is</p> <p>19 that correct?</p> <p>20 A. Yes.</p> <p>21 Q. And you found in the conclusion, this</p> <p>22 was actually presented in the Eastern Vascular</p> <p>23 Society in DC in September of 2011, you found that</p> <p>24 CPIVCF was associated with specific clinical</p> <p>25 features, increased healthcare resource utilization</p>
<p>1 of using filters. I'd like to talk about the</p> <p>2 benefit or the efficacy, if I could, about filters;</p> <p>3 or, in other words, do they work.</p> <p>4 In 2012, you wrote a paper, I think</p> <p>5 it was called Concurrent Prophylactic Placement of</p> <p>6 IVC Filter in Bariatric Patients.</p> <p>7 Do you recall that?</p> <p>8 A. I do.</p> <p>9 Q. And you wrote that along with Dr.</p> <p>10 Gorecki, Semaan, Briggs, Tortolani, correct?</p> <p>11 A. Yes.</p> <p>12 Q. Are they in your department?</p> <p>13 A. Some of them, yes; some of them, no</p> <p>14 longer.</p> <p>15 Q. I'm going to mark this as Exhibit-5.</p> <p>16 - - -</p> <p>17 (Whereupon, Exhibit-5, Eastern</p> <p>18 Vascular Society, Concurrent Prophylactic Placement</p> <p>19 of Inferior Vena Cava Filter In Gastric Bypass and</p> <p>20 Adjustable Banding Operations in the Bariatric</p> <p>21 Outcomes Longitudinal Database, was marked for</p> <p>22 identification.)</p> <p>23 - - -</p> <p>24 THE WITNESS: Thank you.</p> <p>25 MS. HELM: Do you have a copy?</p>	<p>1 and higher mortality in patients undergoing</p> <p>2 bariatric operations. Although selected patient</p> <p>3 characteristics influenced surgeons to perform</p> <p>4 CPIVCF, this study was unable to establish an</p> <p>5 outcome benefit for CPIVCF.</p> <p>6 That was a mouthful.</p> <p>7 A. Yes.</p> <p>8 Q. But can you tell us what that means?</p> <p>9 A. What that means is that there appears</p> <p>10 to be no benefit for morbidly obese patients</p> <p>11 undergoing these procedures to undergo concurrent</p> <p>12 placement of an IVC filter.</p> <p>13 Q. So this filter in these -- in this</p> <p>14 particular study was used prophylactically --</p> <p>15 A. That is correct.</p> <p>16 Q. -- to prevent PE post surgery from a</p> <p>17 patient, correct?</p> <p>18 A. Correct.</p> <p>19 Q. And you found, with your other</p> <p>20 authors, that there was no benefit of the filter?</p> <p>21 A. Correct.</p> <p>22 Q. That's an important finding.</p> <p>23 Do you agree?</p> <p>24 MS. HELM: Object to the form.</p> <p>25 THE WITNESS: Yes.</p>

<p style="text-align: right;">Page 58</p> <p>1 BY MR. MATTHEWS:</p> <p>2 Q. Do you think it was a minor finding?</p> <p>3 MS. HELM: Same objection.</p> <p>4 THE WITNESS: No, I think that was an</p> <p>5 important finding and, hence, the reason why it was</p> <p>6 published in the medical literature.</p> <p>7 BY MR. MATTHEWS:</p> <p>8 Q. All right. There was a study in 1998</p> <p>9 by Dr. Decousus called the PREPIC 1 study.</p> <p>10 Are you familiar with that study?</p> <p>11 A. I am.</p> <p>12 Q. When were you first familiar with the</p> <p>13 study? When did you first see the study?</p> <p>14 A. I don't know that I could answer that</p> <p>15 accurately. I would assume in training or shortly</p> <p>16 thereafter. The early years of clinical practice.</p> <p>17 Q. There was a finding in that study --</p> <p>18 and this was a randomized control trial --</p> <p>19 A. Uh-huh.</p> <p>20 Q. -- correct?</p> <p>21 MS. HELM: Do you have a copy?</p> <p>22 MS. BLAS: Yes.</p> <p>23 THE WITNESS: Thank you.</p> <p>24 - - -</p> <p>25 (Whereupon, Exhibit-6, NEJM, A</p>	<p style="text-align: right;">Page 60</p> <p>1 safe as unfractionated heparin for the initial</p> <p>2 treatment of proximal deep vein thrombosis in</p> <p>3 patients presumed to be at high risk.</p> <p>4 Do you recall reading this -- about</p> <p>5 this study?</p> <p>6 A. I do.</p> <p>7 Q. Have you ever talked to Decousus or</p> <p>8 any of his co-authors from the thrombosis hospital</p> <p>9 in France?</p> <p>10 A. I have not.</p> <p>11 Q. Looking at this study, and there was</p> <p>12 a follow-up, I think, eight years later, but strike</p> <p>13 that --</p> <p>14 A. There was.</p> <p>15 Q. I'm sorry?</p> <p>16 MR. LERNER: He said there was.</p> <p>17 THE WITNESS: I said I'm familiar</p> <p>18 with that.</p> <p>19 BY MR. MATTHEWS:</p> <p>20 Q. Are you familiar with the follow-up</p> <p>21 study that, for all practical purposes, agreed with</p> <p>22 the original study?</p> <p>23 MS. HELM: Object to the form.</p> <p>24 THE WITNESS: I am familiar with the</p> <p>25 PREPIC 2 trial, yes.</p>
<p style="text-align: right;">Page 59</p> <p>1 Clinical Trial of Vena Caval Filters in the</p> <p>2 Prevention Of Pulmonary Embolism in Patients With</p> <p>3 Proximal Deep-Vein Thrombosis, was marked for</p> <p>4 identification.)</p> <p>5 - - -</p> <p>6 BY MR. MATTHEWS:</p> <p>7 Q. I would turn your attention to the</p> <p>8 second-to-the-last page, the bottom right-hand</p> <p>9 corner, last paragraph.</p> <p>10 A. Second-to-last page?</p> <p>11 Q. Yes. And the last full paragraph on</p> <p>12 the bottom right-hand column.</p> <p>13 This was a randomized control trial</p> <p>14 that found, and I'm quoting this study, This study</p> <p>15 demonstrated the initial efficacy of filters for the</p> <p>16 prevention of pulmonary embolism in patients</p> <p>17 presumed to be at high risk who had proximal deep</p> <p>18 vein thrombosis and were receiving you</p> <p>19 anticoagulants. However, because of the observed</p> <p>20 excess rate of recurrent deep vein thrombosis and</p> <p>21 the absence of any effect on mortality among</p> <p>22 patients receiving filters, their systematic use</p> <p>23 cannot be recommended in this population. In</p> <p>24 addition, this study showed that</p> <p>25 low-molecular-weight heparin was as effective and</p>	<p style="text-align: right;">Page 61</p> <p>1 MS. HELM: I'm sorry, can the folks</p> <p>2 on the phone, can you please mute the phones? We're</p> <p>3 getting all kinds of noise.</p> <p>4 Thank you.</p> <p>5 BY MR. MATTHEWS:</p> <p>6 Q. Knowing about the lack of efficacy</p> <p>7 and the fact there was no reduction mortality in</p> <p>8 PREPIC 1 nor PREPIC 2, with the information I've</p> <p>9 shown you that there was a fivefold increased risk</p> <p>10 for fracture with the G2, if you had known that</p> <p>11 prior to implanting Ms. Booker in 2007, would you</p> <p>12 have implanted that G2?</p> <p>13 MS. HELM: Object to the form.</p> <p>14 Mischaracterizes the prior testimony.</p> <p>15 MR. LERNER: It's unclear, are you</p> <p>16 talking about any filter or this particular filter?</p> <p>17 MR. MATTHEWS: I was talking about</p> <p>18 taking into account the lack of efficacy and the</p> <p>19 fact there were no reduction in mortality in PREPIC</p> <p>20 1 and PREPIC 2, coupled with the fact that the G2</p> <p>21 had a fivefold increased risk for fracture compared</p> <p>22 to other filters.</p> <p>23 BY MR. MATTHEWS:</p> <p>24 Q. In 2007 would you have implanted that</p> <p>25 filter?</p>

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<p>1 MS. HELM: Object to the form.      2 MR. LERNER: That particular filter?      3 MR. MATTHEWS: That particular      4 filter.</p> <p>5 THE WITNESS: The PREPIC 1 trial is a      6 great study, and it's a very interesting study. But      7 there are problems in this study, as there are      8 problems with every study. And the fundamental      9 problem that you have with this trial is that it      10 randomized patients who were candidates for caval      11 interruption or not; in other words, all patients      12 were treated with blood thinners. It doesn't really      13 address the question of what to do with those      14 patients that cannot be treated with blood thinners.</p> <p>15 And from my review of the chart on      16 Ms. Booker, it was clear that she could not be      17 treated with blood thinners. The reason for that      18 was she had bleeding complications. She was, if I      19 recall, anemic, and she was to undergo subsequent      20 surgical interventions.</p> <p>21 So her anticoagulation had to be      22 held, hence, PREPIC doesn't really apply to a      23 patient like Ms. Booker. It applies to a different      24 set of patients.</p> <p>25 With regards to the Bard filter,</p>	<p>1 piece of information, as far as making decisions      2 regarding this or any other patient, yes.      3 BY MR. MATTHEWS:      4 Q. And it would have influenced your      5 prescribing habit?</p> <p>6 MS. HELM: Object to the form.      7 THE WITNESS: Yes.</p> <p>8 BY MR. MATTHEWS:      9 Q. Let me show you a study, I'm going to      10 mark this as D'Ayala Exhibit Number 7. And this is      11 entitled, The Prevalence of Fracture -- I'm sorry,      12 let me hand that to you.</p> <p>13 A. Sure.</p> <p>14 Q. The Prevalence of Fracture and      15 Fragment Embolization of Bard Retrievable Vena Cava      16 Filters and Clinical Implications Including Cardiac      17 Perforation and Tamponade.</p> <p>18 - - -      19 (Whereupon, Exhibit-7, AMA,      20 Prevalence of Fracture and Fragment Embolization of      21 Bard Retrievable Vena Cava Filters and Clinical      22 Implications Including Cardiac Perforation and      23 Tamponade, was marked for identification.)</p> <p>24 - - -      25 BY MR. MATTHEWS:</p>
<p>1 would I have used a different device if I knew at      2 the time that the Bard filter was not ideal or as      3 good as some of the other implants? The answer      4 would have to be yes.</p> <p>5 BY MR. MATTHEWS:      6 Q. You would have used --      7 A. I would have used a different filter      8 if there was a different filter that I knew of that      9 was better, in terms of its safety profile.</p> <p>10 Q. In terms of the documents that you      11 have, I think they are Exhibit-2 and 3, the health      12 hazard report and then the investigation conducted      13 by Bard that showed a fivefold increased risk for      14 fracture and embolization of that fracture, and you      15 told us that would be the type of information you      16 would want to know in your benefit/risk analysis,      17 knowing that --</p> <p>18 A. Yes.</p> <p>19 Q. -- and seeing that today, would that      20 have been enough to use another filter?</p> <p>21 MS. HELM: Object to the form.</p> <p>22 THE WITNESS: Difficult to say with      23 certainty. It would depend upon what other filters      24 we had at the time and what their problems would      25 have been. But it would have been a very important</p>	<p>1 Q. The first author in this study is      2 William Nicholson.      3 Do you see that?      4 A. I do.      5 Q. He is from Penn State, Hershey,      6 Pennsylvania, as we see in the bottom left corner.      7 A. Uh-huh.      8 Q. Do you know Dr. Nicholson?      9 A. I do not.</p> <p>10 MR. LERNER: I apologize, is there a      11 date on this?</p> <p>12 MR. MATTHEWS: Yes. This was      13 published in -- on August 9th, 2010.</p> <p>14 MR. LERNER: Thank you.</p> <p>15 BY MR. MATTHEWS:      16 Q. I'm sorry, did I ask you, have you      17 seen this study before?      18 A. I do not believe I have.      19 Q. Under the method, it says that these      20 doctors sought to determine the prevalence of      21 fracture and embolization of the Bard Recovery and      22 the Bard G2 vena cava filter.      23 That's the filter you implanted in      24 Ms. Booker, correct?      25 A. Correct.</p>

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<p>1       Q. A retrospective single-center      2 cross-sectional study was conducted by evaluating      3 all patients who received either a Bard Recovery or      4 Bard G2 filter from April 2004 until January 2009.      5           Under the results it says, 13 of 80      6 patients had at least one strut fracture. At least      7 one strut in 7 of the 28 Bard Recovery filters      8 fractured and embolized. In 5 of the 7 cases,      9 patients had at least one fragment embolize to the      10 heart, 71 percent of those that fractured. Three      11 patients experienced life-threatening symptoms of      12 ventricular tachycardia and/or tamponade, including      13 one patient who experienced sudden death at home.      14 Six of 52 Bard G2 filters fractured, 12 percent. In      15 2 of these 6 cases, the patients had asymptomatic      16 end-organ fragment embolization.</p> <p>17           Did I read that correctly?</p> <p>18       A. Yes, sir.</p> <p>19       Q. Okay. The conclusion of this study      20 by Dr. Nicholson and other doctors in different      21 fields of medicine found the Bard Recovery and Bard      22 G2 filters had high prevalence of fracture and      23 embolization with potentially life-threatening      24 sequelae.</p> <p>25       Doctor, if you had been warned prior</p>	<p>1 studies. I ask you because you use these products.      2 I ask you because you are a researcher to the extent      3 that you have published studies specific to IVC      4 filter.</p> <p>5           MR. MATTHEWS: I don't really think      6 it's an unfair question.</p> <p>7 BY MR. MATTHEWS:</p> <p>8       Q. My question is, do you know of      9 anything that would have presented Bard from      10 conducting the same type of study with the G2 prior      11 to the sale of the G2?</p> <p>12       MS. HELM: Object to the form.</p> <p>13       MR. LERNER: Again, I don't know how      14 he could answer. But if he can answer it, he can      15 answer it. I'm not going to fight with you about      16 it.</p> <p>17       MR. MATTHEWS: If you're      18 uncomfortable with it, I'm going take it back.</p> <p>19       MR. LERNER: I'm not here to argue      20 with you. I just don't think it's a fair question      21 for this doctor to answer what a corporation could      22 or couldn't do at a certain period of time.</p> <p>23       MR. MATTHEWS: Well, all right, then,      24 I'll withdraw it.</p> <p>25       MR. LERNER: Thank you.</p>
<p style="text-align: center;">Page 67</p> <p>1 to June of 2007 of this information, I know this is      2 dated 2010, but I'm going to ask you the question      3 for purposes of a hypothetical, that is, had you      4 known this information of this conclusion, that the      5 G2 had a high prevalence of fracture and      6 embolization with life-threatening sequelae, would      7 that have influenced your prescribing habits and the      8 use of the G2 with Ms. Booker?</p> <p>9           MS. HELM: Object to the form.</p> <p>10          THE WITNESS: Yes.</p> <p>11 BY MR. MATTHEWS:</p> <p>12       Q. Do you know of any reason back after      13 the pilot study in 2002 why Bard could not have      14 conducted a clinical trial with its G2 and done      15 follow-up with patients from the original pilot      16 study?</p> <p>17       MR. LERNER: I'm not sure how --</p> <p>18       MS. HELM: Object to form.</p> <p>19       MR. LERNER: I'm not sure how he's      20 supposed to be able to answer a question like that.      21 That doesn't seem like a fair question for this      22 doctor.</p> <p>23       MS. HELM: I object to the form.</p> <p>24 BY MR. MATTHEWS:</p> <p>25       Q. I ask you because you have conducted</p>	<p style="text-align: center;">Page 69</p> <p>1 BY MR. MATTHEWS:</p> <p>2       Q. On the third page of this study, if      3 you could turn to -- I'm sorry, I think I'd like to      4 turn to the fourth page.</p> <p>5       A. Okay.</p> <p>6       Q. It says E4 on the bottom of it.</p> <p>7       A. Okay.</p> <p>8       Q. On the left-hand column, the first      9 full paragraph. Left hand, first full.</p> <p>10       A. I see it.</p> <p>11       Q. It says, We would contend that the      12 fracture prevalence seen by Cantwell might have been      13 significantly higher if the filter was allowed to      14 remain in place for a longer period. If one were to      15 extrapolate our observed prevalence of Bard G2      16 filter fractures to 50 months, the prevalence of      17 fracture would be identical to that observed for the      18 Bard Recovery filter, thus challenging the      19 hypothesis that the Bard G2 filter represents an      20 improvement in fracture resistance.</p> <p>21       The finding of the fracture rate of      22 the Recovery was 25 percent within this study; 25      23 percent of the filters fractured of the Bard      24 Recovery. These authors, after this study,      25 determined that the fracture rate would be the same</p>

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<p>1 if you extrapolate indwelling time with the G2      2 filter, that making it a 25 percent filter fracture      3 rate for the G2.      4 Do you understand that premise within      5 the paper?      6 A. I think I understand the premise.      7 I'm not so sure that I understand the science behind      8 it.      9 Q. Well, let me ask you this question,      10 then, Doctor: If you knew back in 2007 when you      11 were implanting that filter that there was even a 12      12 percent probability of fracture with that filter,      13 would you have used a G2?      14 MS. HELM: Object to the form.      15 THE WITNESS: Unlikely.      16 BY MR. MATTHEWS:      17 Q. If there was a 25 percent risk of      18 filter fracture, can we safely say you would not      19 have used that filter?      20 A. Most likely. But you have to      21 understand that you have to have a way of treating      22 these difficult patients. So some filter has to be      23 used. And it becomes a matter of deciding which      24 filter is best, so to speak. And sometimes that's      25 not entirely clear.</p>	<p>1 the original.      2 MR. MATTHEWS: That's correct.      3 They're not.      4 MS. HELM: The red boxes were added      5 by --      6 MR. MATTHEWS: The red boxes were      7 added by me for purposes of questioning the witness,      8 and they can be taken out at the time of trial.      9 MS. HELM: I'm just making sure the      10 record is clear --      11 MR. MATTHEWS: No, that's --      12 MS. HELM: -- the red boxes on      13 Exhibit-8 are not part of the original, they were      14 added by plaintiff's counsel.      15 MR. MATTHEWS: Exactly.      16 MR. LERNER: Can we go off the record      17 for just a second?      18 MR. MATTHEWS: Sure.      19 - - -      20 (Whereupon, a discussion off the      21 record occurred.)      22 - - -      23 VIDEO TECHNICIAN: We are now back on      24 the record. The time is 2:13.      25 BY MR. MATTHEWS:</p>
<p>1 MR. MATTHEWS: I'm going to object to      2 the last part of that as nonresponsive.      3 BY MR. MATTHEWS:      4 Q. Doctor, I have pulled medical records      5 from Methodist Hospital to try to pinpoint, so we      6 don't have all of them, and I put them together and      7 made them into an exhibit. And I'll mark it as      8 Exhibit Number 8.      9 - - -      10 (Whereupon, Exhibit-8,      11 BOOKERS_NYMH_MDR00057-461, Medical Records, was      12 marked for identification.)      13 - - -      14 BY MR. MATTHEWS:      15 Q. Just so we're clear, these are select      16 medical records that were pulled that I thought had      17 relevance, and I would like to ask you about some of      18 them.      19 A. Sure.      20 Q. Some of them have your name on them,      21 so I can't read them and I'm hoping you can read      22 your writing.      23 A. Let's try.      24 MS. HELM: For the record, these have      25 red boxes on them. Those red boxes were not part of</p>	<p>Page 71</p> <p>1 Q. Doctor, let me show you what has been      2 marked as Exhibit-11 to your deposition, which is an      3 internal document from Bard.      4 - - -      5 (Whereupon, Exhibit-11,      6 BPV-DEP-00004804-4806, 12/27/05 E-Mail from David      7 Ciavarella to Brian Barry, was marked for      8 identification.)      9 - - -      10 MS. BLAS: I skipped 9.      11 MR. MATTHEWS: That's all right.      12 MS. HELM: It's 11 now.      13 BY MR. MATTHEWS:      14 Q. Doctor, have you had a chance to look      15 at that?      16 A. Uh-huh.      17 Q. I don't want to interrupt you, but --      18 A. Okay.      19 Q. First let me ask you, did you ever      20 use in your practice the Simon Nitinol filter,      21 referred here with an acronym SNF?      22 A. I have.      23 Q. And that is a filter, a permanent      24 filter that was in existence for many years prior to      25 the G2 being cleared by the FDA, correct?</p>

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<p>1        A.    Correct.</p> <p>2        Q.    There is a statement here in the           3 middle, this is an internal document, I'll submit to           4 you, it's an internal document between Bard           5 personnel and the subject matter is the G2 Caudal           6 migrations.</p> <p>7              In the middle of the page it says, I           8 would like to look more generally at the G2           9 complaints. I have seen problems with caudal          10 migration, tilting, perforation, mis-deployment and          11 maybe one or two additional things. Can you tell me          12 the total number of complaints and total number of          13 units distributed?</p> <p>14              Then in the final line it says, The          15 G2 is a permanent filter. We also have one (the          16 SNF) that has virtually no complaints associated          17 with it. Why shouldn't doctors be using that one          18 rather than the G2? Can you also send me the total          19 complaint rate and MDR complaints of the SNF?</p> <p>20              Do you know why -- strike that.</p> <p>21              If the Simon Nitinol filter was          22 available in the hospital, knowing what you know of          23 the documents that I've shown you today, what this          24 company is saying internally to each other within          25 the company, would you have used the Simon Nitinol</p>	<p>1        would you have used the Simon Nitinol instead of the           2 G2 back in 2007?</p> <p>3              MS. HELM: Object to the form.</p> <p>4              MR. LERNER: So if he had that           5 document in 2007, is that the preface of the           6 question?</p> <p>7              MR. MATTHEWS: No. Had he known the           8 information within that document, as well as the           9 information of the other documents that I've shown          10 him today, would he use the Simon Nitinol filter?</p> <p>11              MS. HELM: Object to the form.</p> <p>12              THE WITNESS: When I look at this          13 document, Exhibit-11, that you gave me, all I see is          14 a group of individuals from a particular company          15 questioning a device, in particular its safety with          16 regards to what they're calling caudal migration.          17 It really makes no mention as to complication rates,          18 and the information that is asked for is not          19 included in this document.</p> <p>20              So it would be difficult for me to          21 look at this document and say, boy, this is truly          22 incriminating, at least in my mind. I just look at          23 it as a series of questions between individuals          24 regarding a particular product and its safety.</p> <p>25              I can make nothing of it. If I knew</p>
Page 75	Page 77
<p>1        filter instead of the G2 back in 2007 when you           2 implanted Ms. Booker?</p> <p>3              MS. HELM: Object to the form.</p> <p>4              MR. LERNER: I'm going to ask you to           5 rephrase that. You had a blip in the middle that           6 made the question unclear.</p> <p>7 BY MR. MATTHEWS:</p> <p>8        Q.    Knowing what you know today in           9 viewing Exhibit-11, had you the choice in 2007,          10 would you have used the Simon Nitinol filter instead          11 of the G2?</p> <p>12        MR. LERNER: When you say "the          13 choice," what do you mean by "the choice"?</p> <p>14        MR. MATTHEWS: Would you have used it          15 instead?</p> <p>16        MS. HELM: Object to the form.</p> <p>17        MR. LERNER: Do you understand the          18 question?</p> <p>19        THE WITNESS: I don't.</p> <p>20        MR. LERNER: I don't, either.</p> <p>21 BY MR. MATTHEWS:</p> <p>22        Q.    If you had the Simon Nitinol filter          23 available in 2007, knowing what you know today from          24 these documents that I've shown you, the studies          25 that I've shown you, and this internal document,</p>	<p>1        that one filter was better than the other, as I said           2 before, absolutely, I would use it. I mean,           3 ultimately I don't work for industry, I work for my           4 patients and their -- their interests are my           5 interests.</p> <p>6 BY MR. MATTHEWS:</p> <p>7        Q.    Do you know the material in the Simon          8 Nitinol filter and how it's different from the G2?</p> <p>9        A.    I'm not sure that the material would          10 be any different, in all honesty. I don't recall.          11 But if my memory serves me right, all these filters          12 were made out of nitinol, which is an alloy of          13 nickel, titanium and aluminum.</p> <p>14        Q.    Were the adverse events associated          15 with the nitinol filter or the G2 ever discussed          16 with you by any of the sales reps that called on          17 you?</p> <p>18        MS. HELM: Object to the form.</p> <p>19        THE WITNESS: No. No. But if you ask          20 me to speculate, I would think that it was more the          21 design and not the material of the filter that led          22 to some of these problems that we later saw with          23 fracture and migration.</p> <p>24 BY MR. MATTHEWS:</p> <p>25        Q.    Have you --</p>

<p style="text-align: right;">Page 78</p> <p>1 MS. HELM: Excuse me, I have to move      2 to strike the answer as nonresponsive.</p> <p>3 MR. MATTHEWS: Just object as      4 nonresponsive and you're good.</p> <p>5 BY MR. MATTHEWS:</p> <p>6 Q. Have you looked at design documents      7 or looked at design studies concerning the G2?</p> <p>8 A. No.</p> <p>9 Q. Where do you get the information that      10 you believe it is a design as opposed to a material      11 issue with the G2 fracturing?</p> <p>12 MS. HELM: Object to the form.</p> <p>13 THE WITNESS: If you were to look at      14 pictures of these two filters, they differ      15 substantially in terms of their design. The G2      16 filter has a conical design and the struts all come      17 together at a center point.</p> <p>18 If I remember the Simon Nitinol      19 filter, it's sort of more of a mesh of constant      20 wire, which then attaches to an anchor. So it's a      21 very different design principle. And by virtue of      22 it being, I would suppose, more robust, I think the      23 likelihood of it embolizing is much lower.</p> <p>24 BY MR. MATTHEWS:</p> <p>25 Q. Did you ever have any centering --</p>	<p style="text-align: right;">Page 80</p> <p>1 right-hand column, I'll read out the Bates stamp      2 number, it's MBR93. And I'll tell you it's about      3 the --</p> <p>4 MR. LERNER: The numbers on the      5 bottom right-hand corner of the pages, the Bates      6 stamp.</p> <p>7 MR. MATTHEWS: Yes. It's about the      8 tenth page.</p> <p>9 MS. HELM: They're not in order.</p> <p>10 MR. MATTHEWS: Like I say, I took      11 this many and tried to make it simple.</p> <p>12 MS. HELM: So we're in Exhibit-8,      13 just for the record?</p> <p>14 MR. LERNER: Can you hold it up and      15 show him the page? It might be quicker that way,      16 unless you have it already, Doctor.</p> <p>17 MS. BLAS: It's Exhibit-8, yes.</p> <p>18 THE WITNESS: I am. I'm at Page 63.</p> <p>19 MS. HELM: 93.</p> <p>20 MR. MATTHEWS: Let me do this for      21 you, Doctor, I'm going to make it easier. I'm going      22 to put little stickies on the pages, and that way --</p> <p>23 BY MR. MATTHEWS:</p> <p>24 Q. If we could turn to page Bates stamp      25 MDR93.</p>
<p style="text-align: right;">Page 79</p> <p>1 A. But I don't know that to be a fact.      2 That's not something that I particularly studied.      3 I'm just making assumptions.</p> <p>4 Q. Fair enough. And I just want to know      5 if there's something I needed to find out that you      6 knew.</p> <p>7 But let me ask this: Did you ever      8 have any centering issues with the G2?</p> <p>9 A. All filters have centering issues and      10 they, in part, depend on -- or are determined by the      11 patient's anatomy.</p> <p>12 Q. Were there less centering issues with      13 the Simon Nitinol than there were with the conical      14 G2s?</p> <p>15 MS. HELM: Object to the form.</p> <p>16 BY MR. MATTHEWS:</p> <p>17 Q. In your practice?</p> <p>18 A. I would likely say yes.</p> <p>19 Q. All right. If we could turn to the      20 first page that I see with your name on it.</p> <p>21 A. Okay.</p> <p>22 Q. Because I just want to put on the      23 record what you recognize as your own notes.</p> <p>24 A. Okay.</p> <p>25 Q. And I see that on the bottom</p>	<p style="text-align: right;">Page 81</p> <p>1 Are you there?</p> <p>2 A. Uh-huh.</p> <p>3 MR. MATTHEWS: Is everybody there?</p> <p>4 BY MR. MATTHEWS:</p> <p>5 Q. There's some handwritten notes here.      6 Are these yours?</p> <p>7 A. No.</p> <p>8 Q. Is the bottom right-hand corner      9 yours?</p> <p>10 A. No.</p> <p>11 Q. If we could move to the next one,      12 which is MDR69.</p> <p>13 A. Uh-huh.</p> <p>14 Q. Any of those notes yours?</p> <p>15 A. Yes, that's all written by me.</p> <p>16 Q. Okay. It says, that I can read,      17 Preoperative diagnosis. It's the pre-op note. DVT      18 PE procedure planned, IVC filter. And then      19 pertinent medical history, physical finding.</p> <p>20 A. Uh-huh.</p> <p>21 Q. Can you read that?</p> <p>22 A. It says, Patient with history of DVT      23 PE.</p> <p>24 Q. And then to significant status      25 changes noted. And indication is what?</p>

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<p>1 A. Prevention of PE.      2 Q. And then that's your signature?      3 A. It is.      4 Q. 6/21/07 at 7:30?      5 A. Uh-huh.      6 Q. All right. And the next entry that      7 may or may not be yours, Page 71.      8 A. No, that's -- that's mine.      9 Q. It is? Okay.      10 A. Unmistakable.      11 Q. All right. I think that says,      12 37-year-old with history of DVT PE.      13 A. I'd be happy to translate into      14 English --      15 Q. Yes, please.      16 A. -- if you'd like.      17 6/21/07, vascular attending,      18 37-year-old with history of DVT PE.      19 Q. I'm sorry. On top of that, what does      20 that say? Does that say duplex?      21 A. I'm sorry, you're in the second box?      22 Yes, that says, Duplex chronic left superficial      23 femoral DVT.      24 Q. I apologize. Can we start over on      25 the first box?</p>	<p>1 A. So the way duplex --      2 Q. Externally --      3 A. Correct, it's a non-invasive      4 procedure.      5 Q. Is that the gold standard for      6 determining DVT, would you say?      7 A. It depends upon the clinical      8 scenario. But, yes, it's the imaging modality of      9 choice for lower extremity DVT.      10 Q. If we turn to the next page, this      11 appears to be your op report, correct?      12 A. That is correct.      13 Q. Dated 6/21/07?      14 MS. HELM: For the record, can we      15 identify it by the Bates number, please?      16 MR. MATTHEWS: Yeah, Bates stamped      17 108 and 109. It's a two-page document.      18 MS. HELM: Thank you.      19 BY MR. MATTHEWS:      20 Q. I think this is all legible.      21 A. Indeed.      22 Q. There is a pre-operative diagnosis of      23 DVT and PE. Post-op diagnosis, insertion --      24 operation, insertion of retrievable IVC.      25 That actual -- is that actually</p>
<p>1 A. The top box?      2 Q. Yes, I messed up.      3 A. Sure. 6/21/07, vascular attending,      4 37-year-old with history of DVT PE. Uterine      5 fibroids, vaginal bleed with DVT, despite      6 anticoagulation. Awaiting surgical intervention.      7 Q. Now, it says that, Agree with need      8 for IVC filter.      9 A. Uh-huh.      10 Q. And I believe you told us that that      11 was Dr. Martin with whom you were agreeing with; is      12 that right?      13 A. Yes. Well, to read that entire box      14 it says, 37-year-old awaiting GYN surgery with      15 chronic DVT and PE. Agree with need for IVC filter.      16 Will schedule for insertion of retrievable filter      17 today. Risk/benefits discussed with patient,      18 husband, who agreed to proceed.      19 Q. And when it says, Duplex showed      20 chronic superficial DVT, is that a duplex      21 ultrasound?      22 A. Correct.      23 Q. And that's done -- how is that done?      24 A. Using ultrasound.      25 Q. All right.</p>	<p>1 correct, that it was a retrievable IVC in 2007?      2 A. I can tell you that we had retrieved      3 a number of these G2 filters. I'm not so sure if      4 the company had FDA approval for retrieval of that      5 particular filter.      6 By the IFU, it is incorrect.      7 Q. All right. However, I think it was      8 your testimony that this was implanted as a      9 permanent filter?      10 MS. HELM: Object to the form.      11 THE WITNESS: It was.      12 BY MR. MATTHEWS:      13 Q. A few pages past that, MDR70, there      14 is another note that might be yours.      15 A. Uh-huh.      16 Q. And I believe this says, pre-op,      17 post-op diagnosis DVT PE procedure, IVC filter. No      18 venous anomalies, no caval thrombosis --      19 A. Uh-huh.      20 Q. -- patient's condition stable.      21 I can read that.      22 And then finally on MDR77, the last      23 one, I believe I saw with your name?      24 A. Uh-huh.      25 Q. Can you read that --</p>

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<p>1        A.    Sure.</p> <p>2        Q.    -- for the record, please?</p> <p>3        A.    6/22/07, vascular attending. No</p> <p>4        complaints. Afebrile. Stable vitals. Groin with</p> <p>5        no hematoma. No complaints.</p> <p>6              My apologies. That says, Tolerating</p> <p>7        IVC filter well. Compression stockings.</p> <p>8        Q.    So she went back on anticoagulation</p> <p>9        and stockings post implant?</p> <p>10      A.    The anticoagulation part, I'm not</p> <p>11      sure about. The stockings, yes.</p> <p>12             MR. MATTHEWS: I'll pass the witness.</p> <p>13             MS. HELM: Do you mind if we take a</p> <p>14      break? I think it will go a lot faster if we take a</p> <p>15      break and you give me a few minutes to get</p> <p>16      organized.</p> <p>17             VIDEO TECHNICIAN: We are now off the</p> <p>18      record. The time is 2:32.</p> <p>19             - - -</p> <p>20             (Whereupon, a brief recess was</p> <p>21      taken.)</p> <p>22             - - -</p> <p>23             VIDEO TECHNICIAN: We are now back on</p> <p>24      the record. The time is 2:44.</p> <p>25             - - -</p>	<p>1        Medical Center records?</p> <p>2        A.    No.</p> <p>3        Q.    I believe you mentioned previously</p> <p>4        that you also retrieve IVC filters; is that correct?</p> <p>5        A.    I do.</p> <p>6        Q.    And you also mentioned previously</p> <p>7        that you have retrieved the G2 filter; is that</p> <p>8        correct?</p> <p>9        A.    I have.</p> <p>10      Q.    And do you also place filters that</p> <p>11      are not retrievable filters? Do you also place</p> <p>12      permanent filters?</p> <p>13      A.    No longer.</p> <p>14      Q.    When did you stop placing permanent</p> <p>15      filters?</p> <p>16      A.    It would be difficult for me to say</p> <p>17      with certainty. The practice of IVC filter use has</p> <p>18      been an evolution over the last several years.</p> <p>19      There's been a push away from using IVC filters in a</p> <p>20      small measure based on studies like PREPIC, which</p> <p>21      question the survival advantage associated with the</p> <p>22      use of these filters.</p> <p>23             Today, I would think, across the</p> <p>24      country, far fewer filters are being placed. And</p> <p>25      when they are placed, they are placed, more often</p>
Page 87	Page 89
<p>1             EXAMINATION</p> <p>2             - - -</p> <p>3      BY MS. HELM:</p> <p>4        Q.    Doctor, my name is Kate Helm, and I</p> <p>5        represent CR Bard and Bard Peripheral Vascular in</p> <p>6        this lawsuit.</p> <p>7              We have not met before; is that</p> <p>8        right?</p> <p>9        A.    That's correct.</p> <p>10      Q.    You mentioned that you had reviewed</p> <p>11      records from Methodist Hospital and that you had</p> <p>12      also reviewed records from Gwinnett Medical Center</p> <p>13      in Georgia.</p> <p>14      Those were provided to you by your</p> <p>15      attorney; is that right?</p> <p>16      A.    Yes, ma'am.</p> <p>17      Q.    And do you know how he got them?</p> <p>18      A.    No.</p> <p>19      Q.    Have you had any conversations with</p> <p>20      any attorneys representing Ms. Booker in this</p> <p>21      lawsuit?</p> <p>22      A.    No. Other than today, no.</p> <p>23      Q.    And do you -- were you provided,</p> <p>24      through your attorney, with any other documents</p> <p>25      other than the Methodist records and the Gwinnett</p>	<p>1        than not, for absolute indications as opposed to</p> <p>2        relative indications, which prompted their use in</p> <p>3        the past.</p> <p>4        Q.    Did you ever place the Simon Nitinol</p> <p>5        filter?</p> <p>6        A.    I did, yes.</p> <p>7        Q.    I want you to go ahead -- let's go</p> <p>8        ahead and look at Exhibit-8, which is the records</p> <p>9        from Methodist Hospital.</p> <p>10      A.    Okay.</p> <p>11      Q.    And, specifically, Page 71, which is</p> <p>12      one of your handwritten notes. It probably has a</p> <p>13      sticker on it. It's immediately before the report.</p> <p>14      MR. MATTHEWS: The third sticky.</p> <p>15      MS. HELM: There you go.</p> <p>16      THE WITNESS: Okay.</p> <p>17      BY MS. HELM:</p> <p>18      Q.    In the bottom red box that was made</p> <p>19      by the plaintiff's counsel, when you read your note</p> <p>20      it says "retrievable" -- where it says -- the</p> <p>21      sentence that says "retrievable," what does that</p> <p>22      sentence say?</p> <p>23      A.    Scheduled for insertion of</p> <p>24      retrievable filter today.</p> <p>25      Q.    And in 2007 when you were implanting</p>

<p style="text-align: right;">Page 90</p> <p>1 the filter in Ms. Booker, the G2 filter, you      2 indicated in your note, in your handwritten note,      3 that you were implanting it as a retrievable filter;      4 is that right?      5 A. Yes.      6 Q. And on the next page, on Page 108,      7 which is your op note, under the description of      8 operation, it says, Insertion of retrievable IVC      9 filter.      10 Is that right?      11 A. Uh-huh.      12 Q. And so, again, your operation was the      13 insertion of a retrievable IVC filter; is that      14 right?      15 A. Yes.      16 Q. And the filter that you chose for Ms.      17 Booker was a Bard G2 filter; is that right?      18 A. That's right.      19 Q. And you testified previously that you      20 have retrieved a number of Bard G2 filters?      21 A. I have.      22 Q. Okay. I think you -- it was      23 mentioned earlier that at the time you inserted the      24 Bard G2 filter in Ms. Booker, it had not been      25 cleared by the FDA for retrievability.</p>	<p style="text-align: right;">Page 92</p> <p>1 asking you to think back in time and I understand      2 that, but based on what -- your review of your      3 records and the history you had available to you, do      4 you believe, and the language that you used in your      5 op note and in your handwritten notes, you intended      6 that this filter be retrieved when she was no longer      7 contraindicated for anticoagulants; is that right?      8 A. Yes, based on what I wrote there.      9 MR. MATTHEWS: Object to the form.      10 BY MS. HELM:      11 Q. And I assume that you don't know      12 whether there was any discussion with Ms. Booker or      13 any of her healthcare providers, after you implanted      14 the filter, as to whether it could or should be      15 retrieved; is that right?      16 A. I can tell you that if I intended it      17 to be a retrievable implant, that conversation would      18 have taken place with Ms. Booker.      19 Q. And based on your notes that you      20 discussed the risks and benefits -- again, I'm back      21 on 71 -- with Ms. Booker and that you were      22 scheduling her for a retrievable filter, is it your      23 testimony that it would have been your practice to      24 discuss with her the fact that the filter was      25 retrievable and should be retrieved when she was no</p>
<p style="text-align: right;">Page 91</p> <p>1 Were you aware of that?      2 A. Yes.      3 Q. But you were also aware that it was a      4 filter that you were able to retrieve      5 percutaneously; is that right?      6 A. Yes.      7 Q. You testified earlier that you      8 implanted it as a permanent filter, yet your op      9 notes and your handwritten notes clearly say that      10 you were inserting it as a retrievable filter.      11 So was it implanted as a retrievable      12 filter?      13 A. When --      14 MR. MATTHEWS: Object to the form.      15 THE WITNESS: When I stated that      16 earlier, that was based on my review of the medical      17 record. And my bias, I can tell you today, is to      18 use only retrievable filters and make every effort      19 at retrieving these filters, if possible. Even      20 permanent filters are potentially retrievable with      21 proper techniques, more often than not      22 percutaneously.      23 BY MS. HELM:      24 Q. Looking at the records from Methodist      25 Hospital and the history of Ms. Booker, and I'm</p>	<p style="text-align: right;">Page 93</p> <p>1 longer contraindicated for anticoagulants?      2 MR. MATTHEWS: Object to the form.      3 THE WITNESS: Yes.      4 BY MS. HELM:      5 Q. And as you sit here today, you don't      6 know why her filter wasn't retrieved before 2014, do      7 you?      8 A. I can only guess.      9 Q. We're not asking you to guess.      10 In 2007 when you implanted Ms.      11 Booker's G2 filter, you were aware of the potential      12 complications associated with that filter, were you      13 not?      14 MR. MATTHEWS: Object to the form.      15 THE WITNESS: Of the G2 filter?      16 BY MS. HELM:      17 Q. Yes.      18 A. The reported complications at the      19 time I was aware of, I'm sure.      20 Q. And, in fact, you previously looked      21 at Exhibit-4, which was the IFU --      22 A. Yes.      23 Q. -- for the G2 filter.      24 And you would have had that IFU      25 available to you before you implanted Ms. Booker's</p>

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<p>1 filter, correct?</p> <p>2 A. Yes.</p> <p>3 Q. And, specifically, in Section G of</p> <p>4 the IFU, it discusses that one of the known</p> <p>5 complications of the G2 filter is movement or</p> <p>6 migration; is that right?</p> <p>7 A. It does.</p> <p>8 Q. And it also specifically addresses</p> <p>9 that filter fracture is a known complication of vena</p> <p>10 cava filters, does it not?</p> <p>11 A. It does.</p> <p>12 Q. And, in fact, fracture is a</p> <p>13 complication of all vena cava filters, isn't it?</p> <p>14 A. It is. As is migration.</p> <p>15 Q. Thank you.</p> <p>16 And the G2 -- and the IFU for the G2</p> <p>17 filter that you implanted in Ms. Booker specifically</p> <p>18 says that, There have been reports of embolization</p> <p>19 of vena cava filter fragments resulting in retrieval</p> <p>20 of the fragment using endovascular and/or surgical</p> <p>21 techniques. Most cases a filter fracture, however,</p> <p>22 have been reported without any adverse clinical</p> <p>23 sequelae.</p> <p>24 Is that right?</p> <p>25 A. Uh-huh.</p>	<p>1 would be resumed, or did you have an understanding</p> <p>2 of that?</p> <p>3 A. I'm not entirely sure that that is</p> <p>4 clear to me from the record. I can tell you that it</p> <p>5 would be my practice to discuss resumption of</p> <p>6 anticoagulation with all of the physicians involved</p> <p>7 in her care.</p> <p>8 In this particular case, it would</p> <p>9 depend on no small measure as to the comfort level</p> <p>10 regarding her potential for rebleeding. Keep in</p> <p>11 mind, she came in anemic with a vaginal bleed and</p> <p>12 she came in with DVTs and a pulmonary embolism</p> <p>13 despite anticoagulation.</p> <p>14 Q. Back on Page -- and I apologize, I'm</p> <p>15 jumping around -- but back on Page 71 --</p> <p>16 A. Sure.</p> <p>17 Q. -- in your handwritten note it says,</p> <p>18 Risk/benefits discussed with patient.</p> <p>19 Is that right? I hope that's what it</p> <p>20 says.</p> <p>21 A. Yes.</p> <p>22 Q. Schedule for insertion --</p> <p>23 A. Yes.</p> <p>24 Q. -- of retrievable filter today?</p> <p>25 A. Yes. Risks/benefits discussed with</p>
<p>1 Q. And so before treating Ms. Booker in</p> <p>2 2007, you were aware, as you've stated, that filter</p> <p>3 fracture was a risk associated with a G2 and all</p> <p>4 filters; is that right?</p> <p>5 A. Yes.</p> <p>6 Q. And you took that into consideration</p> <p>7 when weighing the risk/benefit for implanting a G2</p> <p>8 filter in Ms. Booker; is that right?</p> <p>9 A. Yes.</p> <p>10 Q. You testified earlier that Ms.</p> <p>11 Booker, because of what was going on in her medical</p> <p>12 condition, was contraindicated for anticoagulants at</p> <p>13 the time you inserted the filter, correct?</p> <p>14 A. Yes.</p> <p>15 Q. But she had a history of both PE and</p> <p>16 DVT, correct?</p> <p>17 A. Correct.</p> <p>18 Q. And she was about to undergo surgery</p> <p>19 for a cervical mass; is that right?</p> <p>20 A. Right.</p> <p>21 Q. And so she had to be removed from the</p> <p>22 anticoagulant medication?</p> <p>23 A. Right.</p> <p>24 Q. But it was your -- was it your</p> <p>25 understanding that post surgery that medication</p>	<p>1 patient, husband, who agreed to proceed.</p> <p>2 Q. And what was your practice at the</p> <p>3 time, do you recall -- at the time in 2007, what</p> <p>4 risk/benefits would you have discussed with Ms.</p> <p>5 Booker relating to the insertion of the retrievable</p> <p>6 filter?</p> <p>7 A. Right. What I would discuss with any</p> <p>8 young patient regarding any implant is concerns</p> <p>9 regarding durability, procedural complications. I</p> <p>10 would discuss the potential for bleeding, infection;</p> <p>11 a dye reaction, very unlikely, some degree of renal</p> <p>12 insufficiency as the complication of the use of dye.</p> <p>13 And as far as long-term</p> <p>14 complications, as I stated, durability and the</p> <p>15 potential for caval thrombosis, migration,</p> <p>16 fragmentation. Hence, the importance for follow-up</p> <p>17 and attempt at retrieval in the future.</p> <p>18 Q. Was it your practice in 2007, at the</p> <p>19 time you treated Ms. Booker, to inform patients that</p> <p>20 the filter might have to be left permanently or --</p> <p>21 A. Yes.</p> <p>22 Q. -- might be there permanently?</p> <p>23 And because you had identified it as</p> <p>24 a retrievable filter, would you have discussed with</p> <p>25 her how the retrieval of the filter would be</p>

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<p>1 accomplished, if that was to be done?</p> <p>2 MR. MATTHEWS: Object to the form.</p> <p>3 THE WITNESS: Usually, we would tell</p> <p>4 them that that would be a percutaneous procedure,</p> <p>5 similar to the insertion procedure, although</p> <p>6 sometimes not possible.</p> <p>7 BY MS. HELM:</p> <p>8 Q. Did you -- was it your practice in</p> <p>9 2007 to provide the plaintiff or her family member</p> <p>10 with any written materials about the filter or the</p> <p>11 procedure?</p> <p>12 A. No.</p> <p>13 Q. And would you ever give a patient a</p> <p>14 copy of the IFU?</p> <p>15 A. No.</p> <p>16 Q. Why not?</p> <p>17 A. I've never done so. It's just not my</p> <p>18 practice to do so. I think that as a physician when</p> <p>19 you're dealing with a patient, it's really on you to</p> <p>20 make some important decisions for them. And I think</p> <p>21 an IFU is a complicated document. You may correct</p> <p>22 me if I'm wrong, but I think the IFU is mostly</p> <p>23 intended for legal purposes. I'm not so sure it's</p> <p>24 intended to guide medical practice. And I don't</p> <p>25 think its intent is in any way to guide a patient in</p>	<p>1 medical records, did you see, treat Ms. Booker after</p> <p>2 the implantation of the filter?</p> <p>3 A. No. I saw her the day afterwards,</p> <p>4 based on these records, which, as we discussed</p> <p>5 previously, is customary.</p> <p>6 I have no personal office records of</p> <p>7 Ms. Booker ever seeing me after hospital discharge.</p> <p>8 Q. Would it have -- was it your practice</p> <p>9 in 2007 to recommend that a patient come back and</p> <p>10 see you at least once after discharge?</p> <p>11 A. Yes.</p> <p>12 Q. But as far as your records indicate,</p> <p>13 Ms. Booker never did that?</p> <p>14 A. Yes.</p> <p>15 Q. Doctor, at the beginning of the</p> <p>16 deposition you were shown a handful of internal</p> <p>17 documents from Bard, specifically you were shown two</p> <p>18 Bard internal documents and an e-mail.</p> <p>19 Do you recall those?</p> <p>20 A. I do.</p> <p>21 Q. Have you ever been shown internal</p> <p>22 documents from any other device manufacturer?</p> <p>23 A. No.</p> <p>24 Q. Have you ever requested internal</p> <p>25 documents from a device manufacturer in performing a</p>
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<p>1 their decision-making process.</p> <p>2 Q. And I know you have no recollection</p> <p>3 of Ms. Booker and --</p> <p>4 A. No.</p> <p>5 Q. -- no one is questioning that.</p> <p>6 But your notes don't indicate that</p> <p>7 she had any specific questions or concerns, do they?</p> <p>8 A. No.</p> <p>9 Q. Based on your op note and looking</p> <p>10 back at what you can recreate using it, did you feel</p> <p>11 like this was a successful implantation of a G2</p> <p>12 filter?</p> <p>13 A. Yes.</p> <p>14 Q. It appears to be uncomplicated; is</p> <p>15 that right?</p> <p>16 A. Yes.</p> <p>17 Q. And she seemed to have tolerated it</p> <p>18 well?</p> <p>19 A. Yes.</p> <p>20 Q. And there were no post implant</p> <p>21 complications?</p> <p>22 A. Nope.</p> <p>23 Q. As far as you were --</p> <p>24 A. As far as I know.</p> <p>25 Q. Okay. Based on your review of the</p>	<p>1 risk/benefit analysis --</p> <p>2 A. No.</p> <p>3 Q. -- of a product?</p> <p>4 Do you know -- was today the first</p> <p>5 time you had ever seen Exhibits-2 and 3?</p> <p>6 A. Yes.</p> <p>7 Q. And you did not have the opportunity</p> <p>8 to read those exhibits in their entirety, did you?</p> <p>9 A. No.</p> <p>10 Q. But both of the exhibits on their</p> <p>11 face indicate that they are about the Recovery</p> <p>12 filter, do they not?</p> <p>13 A. Indeed.</p> <p>14 Q. And, in fact, the filter that you</p> <p>15 implanted in Ms. Booker was not a Bard Recovery</p> <p>16 filter, was it?</p> <p>17 A. That is correct.</p> <p>18 Q. It was a Bard G2 filter, correct?</p> <p>19 A. Yes.</p> <p>20 Q. And do you -- are you aware of what</p> <p>21 action Bard took as a result of its evaluation of</p> <p>22 the Recovery filter?</p> <p>23 A. No.</p> <p>24 Q. And it looks like Bard was doing an</p> <p>25 internal analyzation of its Recovery filter,</p>

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<p>1 correct?</p> <p>2 A. It does.</p> <p>3 Q. And you don't know what Bard did in</p> <p>4 response to this internal evaluation; is that right?</p> <p>5 A. I do not.</p> <p>6 Q. And you don't know what changes Bard</p> <p>7 made between the Recovery filter and the G2 filter,</p> <p>8 do you?</p> <p>9 A. No.</p> <p>10 Q. I have to ask you very briefly about</p> <p>11 Exhibit Number 11.</p> <p>12 You don't have the context of this</p> <p>13 e-mail, do you?</p> <p>14 A. I have no idea.</p> <p>15 Q. And you don't know what -- how it's</p> <p>16 been explained by company witnesses or anything like</p> <p>17 that, do you?</p> <p>18 A. I do not.</p> <p>19 Q. So there's no way for this internal</p> <p>20 e-mail to -- taken out of context to have any impact</p> <p>21 on your prescribing decisions in making a</p> <p>22 determination about a filter, does it?</p> <p>23 A. No. I think I made that clear</p> <p>24 previously. To me, it seems like a proper</p> <p>25 discussion amongst company officials regarding</p>	<p>1 substantiate that claim; no, I have not.</p> <p>2 Q. Have you ever been provided with</p> <p>3 comparative rate data from manufacturers regarding</p> <p>4 any product that you use, any medical device that</p> <p>5 you use?</p> <p>6 A. Not to my knowledge.</p> <p>7 Q. Have you ever asked for comparative</p> <p>8 rate data on any product or medical device that you</p> <p>9 implant from any manufacturer?</p> <p>10 MS. HELM: Do you need to take that?</p> <p>11 THE WITNESS: Could you excuse me for</p> <p>12 just a moment, please? Thank you.</p> <p>13 MS. HELM: Sure. We'll go off the</p> <p>14 record.</p> <p>15 VIDEO TECHNICIAN: We are now off the</p> <p>16 record. The time is 3:05.</p> <p>17 - - -</p> <p>18 (Whereupon, a brief recess was</p> <p>19 taken.)</p> <p>20 - - -</p> <p>21 VIDEO TECHNICIAN: We are now back on</p> <p>22 the record. The time is 3:08.</p> <p>23 BY MS. HELM:</p> <p>24 Q. Doctor, I was talking to you about</p> <p>25 Exhibits-2, 3 and 11, but particularly 2 and 3.</p>
<p style="text-align: center;">Page 103</p> <p>1 concerns that are arising regarding a particular</p> <p>2 product.</p> <p>3 Q. Fair.</p> <p>4 Are you aware that in this litigation</p> <p>5 that Bard has produced over two million pages of</p> <p>6 documents?</p> <p>7 A. No.</p> <p>8 Q. And Mr. Matthews showed you just a</p> <p>9 handful of pages, didn't he?</p> <p>10 A. Uh-huh.</p> <p>11 Q. And you don't know what the</p> <p>12 explanation is, what the outcome is, what the</p> <p>13 context is of any of these documents, do you?</p> <p>14 A. No.</p> <p>15 Q. And when he asked you previously, if</p> <p>16 you had known certain information would you have</p> <p>17 made a different decision, you don't know whether</p> <p>18 the information he was providing to you was accurate</p> <p>19 or not, do you?</p> <p>20 A. I do not.</p> <p>21 Q. So when he was telling you, for</p> <p>22 example, that the G2 had a five times risk rate for</p> <p>23 fracture compared to other filters, you don't know</p> <p>24 if that's accurate or not, do you?</p> <p>25 A. I have not seen the data that would</p>	<p style="text-align: center;">Page 105</p> <p>1 And I assume that you're also not</p> <p>2 aware that a number of Bard witnesses and employees</p> <p>3 have had their depositions taken --</p> <p>4 A. I am not.</p> <p>5 Q. -- about these documents and the</p> <p>6 actions and information in these documents?</p> <p>7 You're not aware of that, are you?</p> <p>8 A. No.</p> <p>9 Q. And plaintiff's counsel didn't show</p> <p>10 you any of that testimony, did he?</p> <p>11 A. No.</p> <p>12 Q. When it comes to making decisions for</p> <p>13 your patients and weighing the risk and benefits of</p> <p>14 medical devices that you use with your patients, you</p> <p>15 rely on a number of sources, don't you?</p> <p>16 A. I do.</p> <p>17 Q. You rely on the FDA?</p> <p>18 A. Yes.</p> <p>19 Q. You rely on your partners and</p> <p>20 colleagues?</p> <p>21 A. Yes.</p> <p>22 Q. You rely on available medical</p> <p>23 literature regarding the device or the product?</p> <p>24 A. Yes.</p> <p>25 Q. You rely on your own experiences?</p>

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1        A.    I do.	1        you stated that complications from filters -- let me
2        Q.    And you work with a number of	2        make sure I find your language.
3        different medical devices, I think you said as many	3              IVC filter placement is generally
4        as 50; is that right?	4        considered to be a benign procedure with a low
5        A.    Off the top of my head I would say	5        complication rate.
6        yes.	6              Is that right?
7        Q.    And what you rely on is the	7        A.    That is right.
8        manufacturer of medical devices to provide you with	8        Q.    And then you said, Its association
9        reliable information about the device; is that fair?	9        with significant cost and long-term complications is
10      A.    Yes.	10      being increasingly recognized.
11      Q.    And you would not want to receive	11      Right?
12      unreliable or preliminary or internal investigations	12      A.    Yes, ma'am.
13      without knowing the outcome or the results; is that	13      Q.    And, in fact, that's why you
14      right?	14      recommend to patients that you follow-up and that
15      A.    That's right.	15      they have their filters retrieved when they're no
16      Q.    Because getting unreliable or	16      longer needed, correct?
17      incomplete information could harm your patient care,	17      A.    Yes.
18      couldn't it?	18      Q.    Have you ever seen any peer-reviewed
19      A.    It could be misleading, yes.	19      literature saying that the G2 filter has
20      Q.    And it could negatively impact your	20      complication rates that are significantly higher
21      practice, couldn't it?	21      than other filters?
22      A.    Yes.	22      A.    No.
23      Q.    So in making treatment decisions for	23      Q.    So sitting here today, you're not
24      patients, you are not -- you don't rely on	24      aware of any medical literature that shows that the
25      information contained in internal documents from the	25      complication rates for the G2 filter are higher than
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1        medical -- let me start that over. I got lost in my	1        any other filters that were available; is that
2        own question.	2        right?
3              In making treatment decisions for	3        A.    I would rephrase that by saying I
4        your patients, you're not relying on information	4        have not seen any literature that directly compares
5        contained in internal documents from manufacturers	5        the G2 filter to any other filter and states that
6        of medical devices, are you?	6        that filter is more dangerous or less efficacious.
7        A.    No.	7        Q.    Thank you.
8        Q.    It has been suggested to you today	8              Have you ever seen any FDA
9        that Bard Recovery and G2 filters have complication	9        denouncement saying the G2 filter has complication
10      rates that are significantly higher than other	10      rates that are significantly higher than other
11      filters.	11      filters?
12      Do you recall that being suggested to	12      A.    I have not.
13      you?	13      Q.    When we talked about Exhibits-2 and
14      A.    Yes.	14      3, you indicated that it appeared that Bard was
15      Q.    In your own experience, did the G2	15      doing some internal investigation of the Recovery
16      filter have an unexpectedly high complication rate	16      filter; is that right?
17      over other filters?	17      A.    Yes.
18      A.    In the short-term, no; in the	18      Q.    And do you -- in the case of this
19      long-term, I think it is well recognized that those	19      internal assessment, do you know anything beyond
20      filters are associated with a high incidence of	20      what you were able to briefly look at today?
21      fracture and fragment migration. Based on my	21      A.    No.
22      experience, I have not seen a lot of filters	22      Q.    So you don't know how Bard -- what
23      fragment or migrate.	23      conclusions Bard reached or what actions Bard took;
24      Q.    In fact, in one of the articles you	24      is that right?
25      wrote in 2012 -- was it this one or the other one --	25      A.    That's right.

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<p>1       Q. And you don't know whether the FDA      2 was fully satisfied with information it received      3 from Bard and with its continuing to market the      4 Recovery filter despite analysis of complications;      5 is that right?</p> <p>6       A. That's right.</p> <p>7       Q. And you were asked if you knew why      8 the Recovery filter was taken off the market.      9           Do you recall that question?</p> <p>10      A. Yes.</p> <p>11      Q. And do you understand that the G2      12 filter is a second generation?</p> <p>13      A. I do.</p> <p>14      Q. And, in fact, it replaced the      15 Recovery filter?</p> <p>16      A. Indeed.</p> <p>17      Q. So does it make sense to you that      18 when they put the G2 on the market they took the      19 Recovery off the market?</p> <p>20      A. Yes.</p> <p>21      Q. And are you aware that there was a      22 filter that replaced the G2?</p> <p>23      A. I've since stopped using the Bard      24 filters, so I'm not familiar with that particular      25 product.</p>	<p>1 manufacturer should do before bringing a product to      2 market, correct?</p> <p>3       A. Yes.</p> <p>4       Q. You would also agree with me that      5 within -- with any medical device there are risks?</p> <p>6       A. Absolutely.</p> <p>7       Q. And with any medical device there are      8 risks that are -- that are going to be -- that      9 are -- let me not get caught in my own question      10 again -- there are risks that may come to light      11 after the product is on the market?</p> <p>12      A. Yes.</p> <p>13      Q. And the manufacturer's responsibility      14 in that instance is to evaluate those risks and      15 evaluate the product, correct?</p> <p>16      A. Yes.</p> <p>17      Q. And to warn about the risks; is that      18 right?</p> <p>19      A. Yes.</p> <p>20      Q. You were asked previously about      21 whether you ever received a Dear Doctor or Dear      22 Colleague letter from Bard relating to the Recovery      23 filter.</p> <p>24           Do you recall those questions?</p> <p>25      A. I do.</p>
<p style="text-align: center;">Page 111</p> <p>1       Q. Did you ever use the Bard Eclipse      2 filters?</p> <p>3       A. I couldn't say. Perhaps.</p> <p>4       Q. Do you recall when you stopped using      5 Bard filters?</p> <p>6       A. No.</p> <p>7       Q. But if the Eclipse filter was a later      8 generation of the G2, would it make sense to you      9 that Bard took the G2 off the market when it brought      10 the Eclipse to market?</p> <p>11      A. Sure.</p> <p>12      Q. That's something that medical device      13 manufacturers do all the time, right?</p> <p>14      A. Indeed, improve their products, sure.</p> <p>15      Q. And you would expect them to,      16 correct?</p> <p>17      A. I would hope so.</p> <p>18      Q. You would expect them to be looking      19 at reports of adverse events from the -- from      20 patients and analyzing their filters and      21 continuously looking to improve the product; is that      22 right?</p> <p>23      A. Yes.</p> <p>24      Q. And you would agree with me that      25 that's part of the risk/benefit analysis that a</p>	<p style="text-align: center;">Page 113</p> <p>1       Q. If Bard's database indicates that a      2 Dear Doctor letter that went out in December 2004      3 relating to the Recovery filter was sent to you and      4 to Methodist Hospital, you don't have any reason to      5 dispute that, do you?</p> <p>6           MR. MATTHEWS: Object to the form.</p> <p>7           THE WITNESS: I do not.</p> <p>8 BY MS. HELM:</p> <p>9       Q. You just simply don't recall      10 receiving it?</p> <p>11      A. That's exactly right. I simply don't      12 recall receiving it. As you can imagine, I receive      13 a lot of letters, a lot of documents, a lot of      14 e-mails, a good number of which go unread.</p> <p>15      Q. You made a comment earlier about that      16 it was your -- and I can't remember what word you      17 used, but you said that you thought that maybe it      18 was the design of the G2 or the Recovery filter that      19 was different than the SNF that caused it to have      20 different adverse events once it was implanted.</p> <p>21           Do you remember that?</p> <p>22      A. Uh-huh, I do.</p> <p>23      Q. Is that speculation on your part?</p> <p>24      A. Yes.</p> <p>25      Q. And just to make sure, you have never</p>

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<p>1 designed --</p> <p>2 A. No.</p> <p>3 Q. -- an IVC filter, correct?</p> <p>4 A. No.</p> <p>5 Q. And you've never built one?</p> <p>6 A. I just do my best to put them in.</p> <p>7 Q. Thank you.</p> <p>8 Do you recall any specific</p> <p>9 discussions you had with the sales reps from Bard</p> <p>10 regarding the G2 filter?</p> <p>11 A. No.</p> <p>12 Q. Do you recall ever raising any</p> <p>13 questions or concerns with the sales reps regarding</p> <p>14 the G2 filter?</p> <p>15 A. No.</p> <p>16 Q. Your decision to stop using Bard</p> <p>17 filters was based on your review of literature; is</p> <p>18 that right?</p> <p>19 A. It would be based on multiple --</p> <p>20 multiple factors. As I told you before, my personal</p> <p>21 experience was that initially the complication rate</p> <p>22 was low and acceptable. But long-term durability of</p> <p>23 these implants became clear based on reports</p> <p>24 published in the literature, based on discussions</p> <p>25 with colleagues.</p>	<p>1 Q. A Bard filter and another filter.</p> <p>2 A. I have not seen that, no.</p> <p>3 Q. Based on this, you know, the limited</p> <p>4 time you've had with Exhibit-2 and Exhibit-3, do you</p> <p>5 have any reason to believe that Bard wasn't actively</p> <p>6 investigating the incidents at the time it wrote</p> <p>7 these documents in 2004 and January of 2005?</p> <p>8 MR. MATTHEWS: Object to the form.</p> <p>9 THE WITNESS: No.</p> <p>10 BY MS. HELM:</p> <p>11 Q. You were shown a study by Dr.</p> <p>12 Nicholson, it's Exhibit-7.</p> <p>13 And, again, you were not familiar</p> <p>14 with this study; is that right?</p> <p>15 A. I think it's fair to say that that is</p> <p>16 correct.</p> <p>17 Q. And when you implanted the G2 filter</p> <p>18 as a retrievable filter in Ms. Booker in 2007, this</p> <p>19 information from 2010 obviously wasn't available to</p> <p>20 you; is that fair?</p> <p>21 A. Yes.</p> <p>22 Q. Doctor, are you aware that in this</p> <p>23 litigation Dr. Nicholson and his research</p> <p>24 coordinator have had their depositions taken?</p> <p>25 A. No.</p>
<p style="text-align: center;">Page 115</p> <p>1 Q. I want to circle back around, and</p> <p>2 specifically relating to Exhibit-2.</p> <p>3 Do you know if medical device</p> <p>4 manufacturers -- and Exhibit-2, we're talking about</p> <p>5 frequency of adverse events, comparing the Recovery</p> <p>6 filter to other filters.</p> <p>7 Do you know if medical device</p> <p>8 manufacturers are even permitted to provide doctors</p> <p>9 with alleged complication rates, comparative</p> <p>10 complication rates under the FDA guidelines?</p> <p>11 A. I do not.</p> <p>12 Q. And that's not something anyone has</p> <p>13 ever provided to you, though, is it?</p> <p>14 A. No, it is not.</p> <p>15 Q. No sales rep has ever come in and</p> <p>16 said, look at us compared o your competitor; is that</p> <p>17 right?</p> <p>18 A. That is incorrect. Most sales reps</p> <p>19 will come in with the intent of selling a product,</p> <p>20 so they will say, look at us compared to our</p> <p>21 competitor. But, of course, in a more favorable</p> <p>22 light.</p> <p>23 Q. Have they ever shown you alleged</p> <p>24 complication rates comparing the two products?</p> <p>25 A. Which two products?</p>	<p style="text-align: center;">Page 117</p> <p>1 Q. Are you aware that he has produced</p> <p>2 his study documents in this litigation?</p> <p>3 A. No.</p> <p>4 Q. If the testimony of Dr. Nicholson,</p> <p>5 the testimony of his research coordinator and the</p> <p>6 study documents showed that the fractures reported</p> <p>7 in this published study are largely attributable to</p> <p>8 one single implanting physician, that could impact</p> <p>9 the reliability of the conclusions, couldn't it?</p> <p>10 MR. MATTHEWS: Object to the form.</p> <p>11 THE WITNESS: I don't know. I don't</p> <p>12 think I have enough information to be able to answer</p> <p>13 that question. I could think of a number of</p> <p>14 different reasons why one physician would have a</p> <p>15 higher incidence of such complications, the most</p> <p>16 obvious one being he was the principal implanter of</p> <p>17 these devices.</p> <p>18 BY MS. HELM:</p> <p>19 Q. If the patients in the study whose</p> <p>20 filters did not fracture were excluded and only</p> <p>21 patients whose filters fractured were included, that</p> <p>22 would impact the reliability of the conclusions of</p> <p>23 the study, wouldn't it?</p> <p>24 MR. MATTHEWS: Object to the form.</p> <p>25 THE WITNESS: I'm sorry, could you</p>

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<p>1 rephrase that for me?</p> <p>2 MS. HELM: Sure.</p> <p>3 THE WITNESS: I'm not sure I</p> <p>4 understand the question.</p> <p>5 BY MS. HELM:</p> <p>6 Q. If the study -- if in the study they</p> <p>7 only looked at patients whose filters fractured and</p> <p>8 they excluded patients who were part of a study but</p> <p>9 whose filters did not fracture, that would impact</p> <p>10 the reliability of the conclusions, wouldn't it, if</p> <p>11 they self-selected out patients?</p> <p>12 A. Could you further explain that?</p> <p>13 Q. Sure. If the study only analyzes the</p> <p>14 fracture -- the patients whose filters fractured --</p> <p>15 A. Yes.</p> <p>16 Q. -- and did not include the patients</p> <p>17 who were in the study but whose filters did not</p> <p>18 fracture --</p> <p>19 A. Yes.</p> <p>20 Q. -- that would impact the reliability</p> <p>21 of the conclusions; do you agree?</p> <p>22 MR. MATTHEWS: Object to the form.</p> <p>23 THE WITNESS: I'm not sure. I don't</p> <p>24 know that I have enough information to be able to</p> <p>25 answer that question.</p>	<p>1 for you to know, in evaluating Exhibit-7, that in</p> <p>2 2012 Dr. Nicholson published a correction to this</p> <p>3 study?</p> <p>4 A. Yes.</p> <p>5 Q. And in -- and if in that correction</p> <p>6 he acknowledges various errors in the study, that is</p> <p>7 something you would want to know in evaluating it,</p> <p>8 wouldn't you?</p> <p>9 A. Yes. But I think that an educated</p> <p>10 observer should be able to read a paper like this</p> <p>11 and draw those conclusions himself. But, yes, that</p> <p>12 would be pertinent information, and I would like to</p> <p>13 have that, absolutely.</p> <p>14 Q. Are you still implanting filters</p> <p>15 today?</p> <p>16 A. Yes, I am.</p> <p>17 Q. And has your practice changed today</p> <p>18 from 2007?</p> <p>19 MR. LERNER: You'd have to clarify</p> <p>20 that question.</p> <p>21 MS. HELM: Sure. That's fair enough.</p> <p>22 BY MS. HELM:</p> <p>23 Q. As far as follow-up of your patients,</p> <p>24 has your practice changed today from 2007?</p> <p>25 A. Little. Has my practice changed in</p>
<p style="text-align: center;">Page 119</p> <p>1 You have to keep in mind that this is</p> <p>2 a retrospective review of a particular practice and</p> <p>3 their experience with these filters with a</p> <p>4 relatively small number of patients and also a</p> <p>5 relatively small number of complications.</p> <p>6 I don't know that you can base your</p> <p>7 practice off this one report. I think a report like</p> <p>8 this has to be looked at, considered. I haven't had</p> <p>9 enough time to go through it, through their</p> <p>10 statistical methods, through their results to be</p> <p>11 able to give you any intelligent opinion as to</p> <p>12 whether or not I would alter my practice based on</p> <p>13 this one report.</p> <p>14 Just by virtue of the design of the</p> <p>15 study, I would have to say no. It would be something</p> <p>16 that might potentially raise some concerns and cause</p> <p>17 me to think twice, but I'm not so sure that this is</p> <p>18 something that I would take to the bank, so to</p> <p>19 speak.</p> <p>20 BY MS. HELM:</p> <p>21 Q. Fair enough.</p> <p>22 MR. MATTHEWS: Object as</p> <p>23 nonresponsive.</p> <p>24 BY MS. HELM:</p> <p>25 Q. If you were -- would it be important</p>	<p style="text-align: center;">Page 121</p> <p>1 general? Yes, of course. I think we alluded to</p> <p>2 that previously in the sense that we have pushed</p> <p>3 away from using filters and make sure that when we</p> <p>4 use them, we use them in those patients who have</p> <p>5 absolute indications for implantation.</p> <p>6 Q. Doctor, you were asked a number of</p> <p>7 times today, if something is true, would that have</p> <p>8 impacted your decision of whether to use a certain</p> <p>9 filter or not.</p> <p>10 Do you recall those questions?</p> <p>11 A. Yes, I do.</p> <p>12 Q. What you have not been provided today</p> <p>13 is with any peer-reviewed or reliable information</p> <p>14 showing that those "ifs" are, in fact, true; is that</p> <p>15 right?</p> <p>16 MR. MATTHEWS: Object to the form.</p> <p>17 MR. LERNER: That's more a statement</p> <p>18 than a question, don't you think?</p> <p>19 THE WITNESS: I agree.</p> <p>20 BY MS. HELM:</p> <p>21 Q. And for you to make an evaluation and</p> <p>22 to make a decision relating to whether you would</p> <p>23 have done something or not, it would be important</p> <p>24 for you to have reliable and complete information;</p> <p>25 is that right?</p>

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<p>1        A. Yes.</p> <p>2            MS. HELM: That's all I have right</p> <p>3 now.</p> <p>4            MR. MATTHEWS: I have just some quick</p> <p>5 follow-ups.</p> <p>6            THE WITNESS: Okay.</p> <p>7            - - -</p> <p>8            EXAMINATION</p> <p>9            - - -</p> <p>10 BY MR. MATTHEWS:</p> <p>11          Q. You were just asked about</p> <p>12 peer-reviewed information that's been put in front</p> <p>13 of you.</p> <p>14          A. Yes.</p> <p>15          Q. The Nicholson article is a</p> <p>16 peer-reviewed journal article; is that correct?</p> <p>17          A. It is.</p> <p>18          Q. And let me show you the next exhibit,</p> <p>19 which is the VJ study, which is called --</p> <p>20          MS. HELM: What exhibit?</p> <p>21          MS. BLAS: 12.</p> <p>22            - - -</p> <p>23          (Whereupon, Exhibit-12, Fractured</p> <p>24 Bard Recovery, G2, and G2, Express Inferior Vena</p> <p>25 Cava Filters: Incidence, Clinical Consequences, and</p>	<p>1            - - -</p> <p>2            (Whereupon, Exhibit-13,</p> <p>3 Evidence-Based Evaluation of Inferior Vena Cava</p> <p>4 Filter Complications Based on Filter Type, was</p> <p>5 marked for identification.)</p> <p>6            - - -</p> <p>7 BY MR. MATTHEWS:</p> <p>8          Q. This is in Interventional Radiology,</p> <p>9 also a peer-reviewed journal article, by Deso,</p> <p>10 Idakoji and William Kuo.</p> <p>11          If I could turn your attention to the</p> <p>12 Table 2.</p> <p>13          A. Sorry about that, I just wanted to</p> <p>14 read that first paper.</p> <p>15          Q. It's okay.</p> <p>16          I was just trying to move it along,</p> <p>17 but you can take as long as you want.</p> <p>18          Have you seen this article before?</p> <p>19          A. I have not.</p> <p>20          Q. All right. This is from the Division</p> <p>21 of Vascular and Interventional Radiology at Stanford</p> <p>22 University. And this was published in 2012.</p> <p>23          And if I could turn your attention to</p> <p>24 Table 2 on the fifth page.</p> <p>25          A. Okay.</p>
<p>1 outcomes of Removal Attempts, was marked for</p> <p>2 identification.)</p> <p>3            - - -</p> <p>4 BY MR. MATTHEWS:</p> <p>5          Q. It's called, Fractured Bard Recovery,</p> <p>6 G2 and G2 Express Interior Vena Cava Filters,</p> <p>7 Incidence, Clinical Consequences and Outcomes of</p> <p>8 Removal Attempts.</p> <p>9          This is in the Journal of Vascular</p> <p>10 and Interventional Radiology, 2012. That's also a</p> <p>11 peer-reviewed journal article, correct?</p> <p>12          A. It is.</p> <p>13          Q. And the results is -- the results</p> <p>14 are, A total of 63 fractured Recovery, G2, G2</p> <p>15 Express were identified, for an overall fracture</p> <p>16 rate of 12 percent.</p> <p>17          So this is a second peer-reviewed</p> <p>18 journal that talks about the fracture rate of the</p> <p>19 G2, correct?</p> <p>20          A. Correct.</p> <p>21          Q. Let me show you the Deso study, which</p> <p>22 is also a peer-reviewed journal article comparing</p> <p>23 the filters, G2, with other filters, in terms of</p> <p>24 their fracture rate. And we're going to mark this</p> <p>25 as Exhibit-13.</p>	<p>1          Q. This table, Doctor.</p> <p>2          A. Okay.</p> <p>3          Q. I think it's the fifth page or so,</p> <p>4 Page 97.</p> <p>5          A. Okay.</p> <p>6          Q. Have you seen the comparison of</p> <p>7 filters and the fracture rate between filters before</p> <p>8 today?</p> <p>9          MR. LERNER: Are you talking about</p> <p>10 that page?</p> <p>11          THE WITNESS: No.</p> <p>12          MR. MATTHEWS: I'm sorry?</p> <p>13          MR. LERNER: Are you talking about</p> <p>14 that page?</p> <p>15 BY MR. MATTHEWS:</p> <p>16          Q. Well, actually, the question is more</p> <p>17 general than that.</p> <p>18          Have you seen a comparison of</p> <p>19 filters, the fracture rates between published</p> <p>20 journal articles, such as we see in Table 2?</p> <p>21          A. I have not seen this particular paper</p> <p>22 before, and I have not seen data like this before.</p> <p>23          Q. Is that a peer-reviewed journal</p> <p>24 article as well?</p> <p>25          A. It is.</p>

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<p>1 Q. Just a few more questions, Doctor, in      2 response to some questions that you were just asked.      3 Doctors such as yourself, to a      4 certain extent, have to rely on industry to do the      5 proper tests and studies to show safety and efficacy      6 before a product is sold; is that true?</p> <p>7 MS. HELM: Object to the form.</p> <p>8 THE WITNESS: I would say yes.</p> <p>9 BY MR. MATTHEWS:</p> <p>10 Q. Had you known at the time of implant      11 that there was up to a 25 percent risk of a      12 fractured filter in the G2, would you have taken      13 steps to ensure that that filter was retrieved from      14 Ms. Booker after implant?</p> <p>15 A. Yes.</p> <p>16 Q. If you would have known there was up      17 to a 25 percent risk of filter fracture in that G2,      18 as we've seen in the articles in front of you, you      19 would have taken greater steps than what were taken      20 to make sure that filter was removed after implant      21 with that patient on that -- in that year, correct?</p> <p>22 MS. HELM: Object to the form.</p> <p>23 THE WITNESS: Knowing what I today, I      24 think it's safe to answer that question as yes.      25 Given the information we had at hand back then, I'm</p>	<p>1 Q. And not by a device manufacturer?</p> <p>2 A. Yes.</p> <p>3 Q. These two articles that you've just      4 been asked about, Exhibits-12 and 13, you have not      5 had an opportunity to review or examine them, have      6 you?</p> <p>7 A. I have not.</p> <p>8 Q. And I don't know which is which, the      9 Deso evidence based --</p> <p>10 A. That would be 13.</p> <p>11 Q. Okay. That article is a -- are you      12 aware that that article is actually a literature      13 review and not a study?</p> <p>14 A. That's briefly what it looks like,      15 yes, ma'am. But I have not had a chance to read      16 this yet.</p> <p>17 Q. And that article -- and I -- this is      18 a statement not a question.</p> <p>19 A. Yes.</p> <p>20 Q. That article also cites to an article      21 by Dr. Lynch relating to a perforation rate of G2      22 filters.</p> <p>23 I assume you've never spoken with Dr.      24 Lynch about --</p> <p>25 A. I have not.</p>
Page 127	Page 129
<p>1 not so sure anything would have changed. But, yes,      2 we make an effort to follow our patients back then      3 as now.</p> <p>4 BY MR. MATTHEWS:</p> <p>5 Q. Let me ask you about that, in terms      6 of the fracture rate.</p> <p>7 Has Bard ever suggested a protocol      8 for your hospital, knowing what we know today, to      9 follow those patients that had Recovery and G2      10 filters to make sure that they are retrieved once      11 the risk of PE has subsided?</p> <p>12 MS. HELM: Object to the form.</p> <p>13 THE WITNESS: No.</p> <p>14 MR. MATTHEWS: Pass the witness.</p> <p>15 - - -</p> <p>16 EXAMINATION</p> <p>17 - - -</p> <p>18 BY MS. HELM:</p> <p>19 Q. Doctor, the decision of whether or      20 how to treat a follow-up patient, you would agree      21 with me that's a medical decision, wouldn't you?</p> <p>22 A. Yes.</p> <p>23 Q. And it needs to be made by a medical      24 doctor with medical training?</p> <p>25 A. Yes.</p>	<p>1 Q. -- this article or his study; is that      2 right?</p> <p>3 A. That's right.</p> <p>4 Q. So you don't have any way of knowing      5 whether Dr. Lynch actually agrees with the      6 representation of his study in the Deso, Kuo      7 article, do you?</p> <p>8 A. I have not.</p> <p>9 Q. And the other article, the one that      10 starts, Fractured Bard Recovery, we talked about it      11 previously, that's a retrospective case series, is      12 it not?</p> <p>13 A. Yes.</p> <p>14 Q. And you have not had an opportunity      15 to evaluate that or determine whether these doctors'      16 experience was the same as yours with the Recovery      17 or G2 filter; is that right?</p> <p>18 A. That's right.</p> <p>19 Q. So, again, it's a source of      20 information out there, but it's a source of      21 information that you would have to study and      22 evaluate and determine its reliability and impact on      23 your decision-making; is that right?</p> <p>24 A. That's fair to say, yes.</p> <p>25 Q. And you can't -- have not had the</p>

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1 opportunity to do that today?	1 INSTRUCTIONS TO WITNESS
2 A. That's right.	2
3 MS. HELM: That's all I have.	3 Please read your deposition over
4 MR. MATTHEWS: I think we're done.	4 carefully and make any necessary corrections. You
5 Thank you.	5 should state the reason in the appropriate space on
6 THE WITNESS: Thank you.	6 the errata sheet for any corrections that are made.
7 VIDEO TECHNICIAN: This concludes	7 After doing so, please sign the
8 today's deposition. The time is 3:37. We are off	8 errata sheet and date it.
9 the record.	9 You are signing same subject to the
10 - - -	10 changes you have noted on the errata sheet, which
11 (Whereupon, the deposition was	11 will be attached to your deposition.
12 concluded at 3:37 p.m.)	12 It is imperative that you return the
13 - - -	13 original errata sheet to the deposing attorney
14	14 within thirty (30) days of receipt of the deposition
15	15 transcript by you. If you fail to do so, the
16	16 deposition transcript may be deemed to be accurate
17	17 and may be used in court.
18	18
19	19
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22	22
23	23
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Page 131	Page 133
1 CERTIFICATE	1 - - - - -
2	2 E R R A T A
3	3 - - - - -
4 I HEREBY CERTIFY that the witness was	4 PAGE LINE CHANGE
5 duly sworn by me and that the deposition is a true	5 _____
6 record of the testimony given by the witness.	6 REASON: _____
7	7 _____
8	8 REASON: _____
9	9 _____
10 Amanda Maslynsky-Miller	10 REASON: _____
11 Certified Realtime Reporter	11 _____
12 Dated: March 27, 2017	12 REASON: _____
13	13 _____
14	14 REASON: _____
15	15 _____
16 (The foregoing certification of this	16 REASON: _____
17 transcript does not apply to any reproduction of the	17 _____
18 same by any means, unless under the direct control	18 REASON: _____
19 and/or supervision of the certifying reporter.)	19 _____
20	20 REASON: _____
21	21 _____
22	22 REASON: _____
23	23 _____
24	24 REASON: _____
25	25 _____

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1 I, \_\_\_\_\_, do hereby  
2 certify that I have read the foregoing pages, 1 -  
3 130, and that the same is a correct transcription of  
4 the answers given by me to the questions therein  
proposed, except for the corrections or changes in  
form or substance, if any, noted in the attached  
Errata Sheet.

5

6

MARCUS D'AYALA, M.D. DATE

7

8

Subscribed and sworn  
to before me this  
\_\_\_\_ day of \_\_\_\_\_, 20\_\_\_\_.

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My commission expires: \_\_\_\_\_

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Notary Public

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1 LAWYER'S NOTES

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